UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA DIRECT PURCHASER **ANTITRUST LITIGATION**	**No. 15-cv-7488-CM** **FILED UNDER SEAL**

DEFENDANTS' CORRECTED MEMORANDUM IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT

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MISCELLANEOUS

Discovery in this complex case brought against pioneer pharmaceutical company Forest has revealed that the dispositive issues are actually straightforward, and no trial is warranted.

On the allegation of a reverse payment, the Court crystallized the issue in its Motion to Dismiss ruling: "Defendants are correct that, viewed in isolation, the settlement terms do not appear anticompetitive." *Sergeant's Benevolent Ass'n Health & Welfare Fund v. Actavis plc*, No. 15-cv-06549, 2016 U.S. Dist. LEXIS 128349, at *50 (S.D.N.Y. Sept. 13, 2016) ("*Namenda I*"). "To survive a motion for summary judgment, Plaintiffs will have to substantiate these allegations with evidence suggesting that the settlement agreements *did, in fact, delay generic entry* and that the delay had the effect of allowing Forest to complete the hard switch." *Id.* at *50-51 (emphasis added). But the undisputed evidence shows just the opposite—Forest and Mylan settled the patent litigation on terms that Plaintiffs ("DPPs") do not (and cannot) seriously contest: three months early entry, $2 million for litigation costs, and an industry standard acceleration clause, allowing Mylan to enter even earlier if the patent was subsequently successfully challenged.

Although DPPs and their experts do take issue with a business transaction related to Lexapro (a separate Forest product) that the parties executed at the same time as the patent settlement, there is no triable issue that that transaction was anything other than a "fair value" business deal of the type explicitly encouraged by the Supreme Court in *Actavis*. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236 (2013) (explaining the "redeeming virtues" of "fair value" transactions done with settlement, which do not raise "the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement"). While Plaintiffs may suggest that a transfer of value of up to $30.9 million (a tiny fraction of Forest's projected profits) was nefarious, such an oversimplification ignores the undisputed fact

that Forest also received considerable value as a result of the heavily negotiated transaction. DPPs do not (and cannot) dispute that the transaction allowed Forest to reduce its expected rebate exposure to Medicaid by at least $26 million, and that Forest's contemporaneous financial forecasts relied on by senior management at the time of the business deal with Mylan projected another $21.1 million in additional royalty payments to Forest resulting from the transaction.

When this business deal with Mylan is properly viewed for what it was—a bona fide, arm's length transaction hammered out between two sophisticated parties, and not a cover up for a "large and unjustified" payment—all DPPs are left with are the provisions of the patent settlement agreement with Mylan. Tellingly, those terms are substantially similar to the terms of the settlements with all the other first filers. And for good reason—following a victory for Forest in the Markman hearing, the generic defendants all began to fold their tents in exchange for three months early entry and payment of minimal litigation costs never exceeding $2 million. Forest steadfastly offered three months early entry and minimal litigation cost payments to *every first filer, including Mylan*, and the record is clear that Forest never budged on this standard offer, reflecting the strength of its patent case. *Actavis*, 133 S. Ct. at 2236-37 ("In a word, the size of the unexplained reverse payment can provide a workable surrogate for the patent's weakness . . . ."). Thus, there is no question that the settlements, did *not*, "in fact, delay generic entry," and the theories of DPPs' experts that generic entry would have occurred much earlier in the but-for world have *zero support* in the undisputed factual record, and therefore amount to nothing more than rank speculation by legal experts. *Namenda I*, at *50-51. Not surprisingly, Plaintiffs have apparently abandoned their allegations related to all settlement agreements other than the Forest/Mylan settlement, offering *no expert opinion* on any of them.

The Court was unwilling to dismiss the reverse payment allegation in the pre-discovery phase under *Actavis* and Judge Abrams's decision in *In re Actos End Payor Antitrust Litigation* (2015 U.S. Dist. LEXIS 127748 (S.D.N.Y. Sept. 22, 2015)) because the allegations were "idiosyncratic" in alleging a two-part scheme when coupled with the hard switch allegations. *Namenda I*, at *49. But there is simply no evidence of an overall scheme hatched in 2010 that included pay-for-delay and a hard switch. And such a scheme would have been impossible by DPPs' own concession that the decision to do the hard switch was made *at least three years after* the Mylan patent settlement. Thus, there is nothing idiosyncratic here, just run-of-the-mill patent settlements, easily disposed of under *Actavis* and *Actos.*

Finally, by the admission of their own experts, DPPs have similarly failed to comply with the clear guidance set out by the Court to prove injury for their hard switch allegation. The Court stated that DPPs must prove that "patients switched to Namenda XR *because of* the announced withdrawal of Namenda IR . . . ." *Id.* at *38 (emphasis added). But both of DPPs' economists analyzing the issue admitted that they made *no attempt* to isolate the effects of the withdrawal announcement, and have instead propounded theories based on market-wide averages of Namenda XR prescriptions. This is an unsophisticated analysis masquerading as real economics, and it fails to distinguish the effects of the announcement from numerous other reasons for Namenda XR adoption, such as the inherent benefits of this improved product, and Forest's indisputably legal "soft-switch" promotional efforts and deep discounting.

Summary judgment for Actavis plc, Forest Laboratories, LLC, Forest Laboratories, Inc., and Forest Laboratories Holdings Ltd. (collectively, "Forest") is warranted and should be granted.

FACTUAL BACKGROUND

A. Alzheimer's Disease, Namenda, the '703 Patent, and Pediatric Exclusivity

1. Namenda IR

In December 2002, Forest submitted New Drug Application ("NDA") No. 21-487 to the FDA, seeking approval to market memantine hydrochloride tablets (5mg and 10mg) ("Namenda" or "Namenda IR") for the treatment of Alzheimer's. Defendants' Statement of Undisputed Facts ("DSUF") ¶ 44. On October 16, 2003, the FDA approved the NDA. DSUF ¶ 45.

2. The '703 Patent

U.S. Patent No. 5,061,703 ("'703 Patent") was issued to Merz + Co. GmbH & Co., which, in turn, licensed the '703 patent to Forest in June 2000. DSUF ¶ 12. On December 9, 2003, Forest submitted a Request for Extension of Patent Term under 35 U.S.C. § 156 for the '703 patent (the "PTE Application") to the U.S. Patent and Trademark Office ("PTO"). DSUF ¶ 28. Further, on August 18, 2004, Forest filed for reexamination of the '703 patent, disclosing several articles for the PTO to consider in deciding whether the claims were patentable. DSUF ¶¶ 13-14. After amending its claims, the PTO issued Forest a reexamination certificate on November 7, 2006. DSUF ¶ 18. On March 18, 2009, the PTO issued a Certificate Extending Patent Term Extension under 35 U.S.C. § 156 for the '703 patent, extending the term of the '703 patent from April 11, 2010 to April 11, 2015. DSUF ¶ 41.

3. Pediatric Exclusivity

On July 7, 2011 Forest submitted a request to Federal Drug Administration ("FDA") to initiate FDA's review and issuance of a Written Request to conduct studies of memantine hydrochloride in pediatric patients with autism. DSUF ¶ 61. At that time, memantine was already being used off-label for this purpose. DSUF ¶ 63. Forest spent approximately $70 million conducting those studies. DSUF ¶ 63. FDA granted Forest six-months Pediatric

Exclusivity on this basis, running from the expiration of the term of the '703 patent on April 11, 2015 to October 11, 2015. DSUF ¶¶ 68-69.

B. The Namenda Patent Litigation and the Claim Construction Ruling

In late 2007 and early 2008, at least fifteen generic pharmaceutical companies (including Teva Pharmaceuticals USA Inc. ("Teva"); Cobalt Laboratories, Inc.; Barr Laboratories Inc. ("Barr"); Orchid Healthcare ("Orchid"); Lupin Pharmaceuticals, Inc. ("Lupin"); Upsher-Smith Laboratories; Wockhardt USA Inc. ("Wockhardt"); Genpharm LP ("Genpharm"); Mylan Pharmaceuticals Inc. ("Mylan"); Interpharm Inc ("Amneal"); Ranbaxy Laboratories Limited ("Ranbaxy"); Sun India Pharmaceutical Industries Limited ("Sun"); Dr. Reddy's Laboratories Inc. ("DRL"); Synthon Labs; and Apotex Inc. (collectively "Generic Defendants") notified Forest of their Abbreviated New Drug Applications ("ANDAs") filed with the FDA, each seeking approval to market a generic version of Namenda IR before the expiration of the '703 patent. DSUF ¶ 281. The vast majority of these were "first filers" who submitted "Paragraph IV" certifications, claiming that the '703 patent was invalid or that their products would not infringe it. DSUF ¶¶ 75-77. Forest responded by filing several patent infringement lawsuits in the District of Delaware in early 2008, asserting infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A), (b) and (c). DSUF ¶¶ 75-76, 281-82. The court eventually consolidated virtually all of the cases into a single action. DSUF ¶ 283.

After substantial briefing and a hearing, Magistrate Judge Stark issued a "Markman" Report and Recommendation on claim construction on July 2, 2009. DSUF ¶¶ 78, 286. In his Report he explained that he "largely sided with [Forest]" and rejected virtually all of the generics' claim construction arguments, including their attempt to secure a finding of noninfringement by limiting the '703 patent to stroke, rather than Alzheimer's disease. DSUF ¶¶

79, 287-89. District Judge Sleet adopted essentially all of Magistrate Judge Stark's recommendations on September 21, 2009. DSUF ¶ 292. Forest viewed this Markman decision as a significant victory for Forest. DSUF ¶ 294. The Generic Defendants apparently agreed. When Magistrate Judge Stark issued his Report and Recommendation, eleven of the fifteen generic companies were in the consolidated case (after one agreed to a voluntary dismissal, two withdrew their ANDAs, and one was transferred). DSUF ¶ 293. Within three months of Judge Sleet's claim construction decision, just one generic company (Mylan) remained. DSUF ¶ 295. Nine of the eleven had settled with Forest, while the tenth (Genpharm) simply gave up and voluntarily withdrew its ANDA. DSUF ¶¶ 294-96.

C. The Settlement Agreements

The settlements with the eleven Generic Defendants were nearly identical, allowing them to enter the market three months before Forest's exclusivity would end—or even earlier if another generic was able to obtain an earlier entry date (the "Generic Entry Acceleration Clause"). DSUF ¶¶ 82, 86, 88, 90, 92, 95, 96, 100, 102, 105, 107, 111, 112, 115, 117, 121, 123, 127, 129, 132, 134, 138, 140, 143, 337. Forest agreed to make payments for litigation costs, not exceeding $2 million in any settlement. DSUF ¶¶ 87, 94, 98, 104, 109, 114, 119, 125, 131.

Forest filed the settlement agreements and two business agreements with Orchid and Mylan with the Federal Trade Commission, who brought no enforcement action. Silber (Mylan) Dep. 11:6-12:3.

D. The Ceftaroline Development and Supply Agreement

Ceftaroline fosamil ("ceftaroline") is the API in the brand drug Teflaro sold by Forest. DSUF ¶¶ 74, 146-47. By 2008, Forest was searching for a secondary supplier of ceftaroline. DSUF ¶ 152. Forest met with numerous potential suppliers and began negotiating with Orchid

to be a potential secondary supplier of ceftaroline API in February 2008 (DSUF ¶ 154-55) and, on November 24, 2008, executed a Memo of Understanding with Orchid to explore a possible collaboration in this regard. DSUF ¶ 156. In May 2009, Forest employees went to India to visit the facilities of Orchid, DRL, Lupin, and Wockhardt to evaluate them as potential ceftaroline API suppliers. DSUF ¶ 159. Forest believed Orchid had the "best facility for a supplier." DSUF ¶ 160. On March 23, 2010, Forest and Orchid executed a Development and Supply Agreement for Ceftaroline Binding Term Sheet ("Ceftaroline Term Sheet"). DSUF ¶ 161.

Under the Ceftaroline Term Sheet, Forest agreed to make payments to Orchid if Orchid was able to reach certain milestones, and a consulting/service fee of $2 million. DSUF ¶¶ 162-63, 168. The price of the API contemplated by the Ceftaroline Term Sheet represented significant cost savings for Forest compared to Forest's incumbent API supplier. DSUF ¶ 167. Orchid, however, was unable to complete the milestones. DSUF ¶ 170. As such, Forest made some, but not all of the payments under the agreement. DSUF ¶¶ 171-72.

E. The Original Lexapro Agreement, Lexapro Amendment, and Forest's Motivations to Modify the Agreement

1. Original Lexapro Agreement

On October 3, 2005, Forest and Alphapharm Pty, Ltd. ("Alphapharm") entered into a Distribution and Supply Agreement that granted Alphapharm the exclusive right to market an Authorized Generic ("AG") version of Forest's escitalopram product, Lexapro ("Original Lexapro Agreement"). DSUF ¶¶ 182-84. An AG is a drug that is manufactured and marketed under the same NDA as a brand drug but is sold as a generic version. DSUF ¶ 183. Alphapharm was later acquired by Mylan. DSUF ¶ 218.

Under the Original Lexapro Agreement, Forest agreed to manufacture and supply Alphapharm's requirements of Lexapro AG. DSUF ¶ 187. Alphapharm was allowed to enter on

February 29, 2012, two weeks before patent expiry. DSUF ¶¶ 188, 193. Under the Original Lexapro Agreement, Alphapharm was required to pay Forest 40% of its "product profit," defined as net sales less Forest's manufacturing costs. DSUF ¶¶ 189-90. Although the full term of the agreement was five years, Alphapharm had the right to terminate after one year. DSUF ¶ 196.

2. The 2005 Deficit Reduction Act of 2005

The Deficit Reduction Act of 2005 ("DRA") amended the definition of Medicaid "Best Price" to include the lowest price of an authorized generic drug. DSUF ¶ 206. Under the DRA, "the primary manufacturer include the best price of an authorized generic drug in its calculation of best price when the drug is being sold by the primary manufacturer to the secondary manufacturer." DSUF ¶ 207. The Original Lexapro Agreement therefore exposed Forest to substantially more Medicaid liability than when it entered the Original Lexapro Agreement in 2005. DSUF ¶¶ 206, 208-11, 214.

3. Forest's Concerns About "Best Price" Liability

Forest was concerned about the substantial Best Price exposure under the 2005 Lexapro Agreement. DSUF ¶¶ 214, 220-23. As such, Forest executives understood that they would need to renegotiate the agreement to address the Best Price issue inherent in Forest manufacturing an AG to be sold by Mylan. DSUF ¶¶ 220-22. As early as July 2009, prior to any settlement negotiations with Mylan related to Namenda, Forest discussed internally the need to modify the Original Lexapro Agreement to address the Best Price liability by having Mylan take over as the primary manufacturer of the Lexapro AG. DSUF ¶¶ 220, 257.

4. Forest's Motivations to Modify the Original Lexapro Agreement

Forest's analysis estimated that it would save $30,437,000, over nine quarters, ($26,467,000 of which would be saved over the first five quarters), if it was to amend the Original Lexapro Agreement to require Mylan take over the manufacturing of the Lexapro AG.

DSUF ¶ 232. Forest and Mylan began negotiating an amendment in early 2010. DSUF ¶ 279. During the same period, a largely separate group of individuals were negotiating the Namenda IR patent settlement agreement. DSUF ¶¶ 275, 279. In early 2010, Forest executives believed that they could enter into business agreements simultaneously with ANDA patent settlements so long as the business agreements were justified as standalone, arm's length transactions that provided fair value to both sides. Solomon (Nov. 15) Dep. 420:11-421:11.

Forest also sought to modify the Original Lexapro Agreement's termination clause. DSUF ¶¶ 236, 264. Forest sought to secure a commitment from Mylan to sell the Lexapro AG for a second year, hoping to capitalize on Mylan's size, reputation, and capability as a generic manufacturer with the two-week first-mover advantage. DSUF ¶¶ 245-49. Absent such an amendment, Forest expected that Mylan would terminate the agreement as soon as the Original Lexapro Agreement's one-year minimum term expired, as Mylan had tentative approval for its own generic Lexapro product. DSUF ¶¶ 246, 249; Expert Report of Philip Green ("Green Rep."), ¶ 42. Because Mylan could sell its own generic product after one year, and thus avoid paying Forest 40% of the product profits, it would be advantageous to Mylan to cease selling Lexapro AG under the Original Lexapro Agreement at the end of a year. DSUF ¶ 247. If the minimum term of the Original Lexapro Agreement were extended by a year, Forest forecasted that it would earn an additional $21.1 million in net profit share (after paying a profit share to Lundbeck, the original product licensor). DSUF ¶ 248.

5. The 2010 Lexapro Amendment with Mylan

On July 21, 2010 Forest and Mylan executed an Amendment to Distribution and Supply Agreement ("Lexapro Amendment"). DSUF ¶ 255. The Lexapro Amendment shifted manufacturing responsibilities for Lexapro AG to Mylan. DSUF ¶ 257. The Lexapro

Amendment also required Forest to make a $20 million payment to Mylan "[i]n consideration for the amendments and modifications to the [Original Lexapro Agreement] . . . and for the undertakings of Mylan with respect to Manufacturing of [Lexapro AG]." DSUF ¶ 260. The Amendment also modified the definition of "Product Profit" to be based on Mylan's manufacturing costs, not Forest's. DSUF ¶ 262. Additionally, the parties modified the 40% profit share from the Original Lexapro Agreement. DSUF ¶ 189, 236, 263. Under the Lexapro Amendment, Mylan agreed to pay Forest a profit share on a graduated scale of 30% on the first $100 million of cumulative product profit, 35% on the next $50 million of cumulative product profit and 40% for cumulative product profit in excess of $150 million. DSUF ¶ 263. The minimum term was also extended from one to two years. DSUF ¶ 264.

Prior to executing the Lexapro Amendment, Forest prepared a series of analyses that forecasted the financial impact of the amendment in three important ways: (1) shifting manufacturing responsibilities to Mylan; (2) extending the minimum term from one to two years; and (3) amending the fixed 40% profit share to the graduated scale described above. DSUF ¶ 236. Forest relied on these analyses to assess and negotiate the Lexapro Amendment with Mylan. DSUF ¶¶ 237-38. The forecasts projected that under the Lexapro Amendment, Forest would incur the cost of the $20 million lump sum payment, and reduced profit share revenues of $12.5 million. DSUF ¶ 265. But Forest would gain an expected $21.1 million of additional profit share revenue in year two, and an expected $26.5 million savings in Medicaid rebate exposure. DSUF ¶ 265.

6. Mylan's Threatened Antitrust Complaint

On February 19, 2010, Mylan sent Forest a draft antitrust complaint, alleging antitrust violations in connection with the '703 Patent. DSUF ¶ 267-68. Mylan's antitrust complaint

risked exposing Forest to treble damages and the cost of defending a complex antitrust suit. DSUF ¶ 270. Mylan released its potential antitrust claims in its patent settlement agreement with Forest. DSUF ¶¶ 271-72. A portion of the consideration paid to Mylan in connection with the Lexapro Amendment was in consideration for Mylan releasing its antitrust allegations against Forest. DSUF ¶ 273.

F. The Introduction of Namenda XR

Forest invested approximately $175 million in developing Namenda XR, the "improved version of Namenda," in a once-daily extended release formulation to conform to prescribers' preferences for once-a-day treatments for Alzheimer's patients. DSUF ¶¶ 48, 359. The FDA approved Namenda XR on June 21, 2010 for use in patients with moderate to severe Alzheimer's disease. DSUF ¶ 51. Forest launched Namenda XR in June 2013. DSUF ¶ 358.

1. Namenda XR Marketing

As part of the Namenda XR launch, Forest aggressively promoted Namenda XR, spending "$120 million educating patients, caregivers, health care providers, and pharmacists about Namenda XR, including Namenda XR's benefits." DSUF ¶ 363. This aggressive promotional effort included advertising in wholesalers' circulars to pharmacists, for which wholesalers were compensated (DSUF ¶ 365), the expansion of the Namenda XR sales force (DSUF ¶ 366), and increased sales representative compensation for Namenda XR conversions. DSUF ¶ 366. Eventually, Forest launched a direct-to-consumer advertising campaign for Namenda XR. Expert Report of Lona Fowdur, Ph.D ("Fowdur Rep."), ¶ 117.

2. Favorable Formulary Placement for Namenda XR

Forest undertook extensive negotiations with health plans to obtain "preferred brand" status for Namenda XR on drug formularies. DSUF ¶ 371. Forest viewed "preferred brand" formulary placement as essential for drug adoption because the failure to place a drug on the

"preferred brand" tier significantly hinders the overall pool of patients that can access the drug at affordable prices. DSUF ¶ 372. As of July 1, 2013, Namenda XR had Medicare Part D formulary coverage for six of the nation's top ten Medicare Part D health plans, and two of the top ten commercial health plans. DSUF ¶ 373. By January 1, 2014, nine of the nation's top health plans had added Namenda XR to the "preferred brand access" tier of their Medicare Part D formularies; these additions resulted in Namenda IR and XR being placed on the same tier for 78.5% of all Medicare Part D prescriptions. DSUF ¶ 374. Forest achieved similar results for formulary placement on health plans' commercial formularies. DSUF ¶ 375. To achieve its goal of comparable formulary coverage to Namenda IR, Forest deeply discounted Namenda XR to health plans. DSUF ¶ 376.

G. The February 2014 Thwarted Withdrawal Announcement

In February 2014, Forest's CEO Brent Saunders made the decision to withdraw Namenda IR from the market. DSUF ¶ 404. On February 14, 2014, Forest issued a press release publicly announcing the benefits of Namenda XR and Forest's plan to discontinue the sale of Namenda IR tablets effective August 15, 2014. DSUF ¶ 405.

1. The 2014 Namenda XR Shortage Continued-Availability Announcement

In the summer of 2014, Forest experienced a shortage in its Namenda XR supply due to manufacturing issues. DSUF ¶ 410. On June 10, 2014, Forest accordingly announced that it would delay the withdrawal of Namenda IR. DSUF ¶¶ 411. The Namenda XR conversion rate began to decline after July 2014. DSUF ¶ 412.

2. The Standstill Agreement

On September 15, 2014, the New York Attorney General ("NYAG") sued Forest to prevent Forest from withdrawing Namenda IR from the market ("NYAG Action"). Compl., *New York v. Actavis*, No, 14-cv-07473, 2014 U.S. Dist. LEXIS 172918 (S.D.N.Y. Dec. 11, 2014)

(ECF No. 1). On September 23, 2014, Forest announced a standstill, suspending withdrawal of Namenda IR until the court's decision on the NYAG's preliminary injunction motion. DSUF ¶ 415.

H. The December 2014 Injunction

On December 15, 2014, Judge Sweet of the Southern District of New York entered an injunction in the NYAG Action. DSUF ¶ 416. Under the injunction, Forest was required to (1) continue to make Namenda IR tablets available on the same terms and conditions applicable since the date Namenda XR entered the market; and (2) inform healthcare providers, pharmacists, patients, caregivers, and health plans of the injunction in the same or substantially similar manner in which Forest informed the market of Forest's plan to discontinue Namenda IR in February 2014. DSUF ¶¶ 416-17. In short, the injunction required Forest to undo the effects of the February 2014 announcement. DSUF ¶ 419. Forest fully complied with the injunction. DSUF ¶¶ 422, 493-94.

1. <u>January 2015 Continued-Availability and Subsequent Announcements</u>

Beginning in January 2015, Forest sent caregivers, health care providers, long term care facilities, and health plans over 900,000 communications alerting them of the injunction and the continued availability of Namenda IR. DSUF ¶¶ 424, 426. Forest sent these communications to the same individuals and entities who had received the February 2014 announcement, to ensure that they would be aware of the injunction and continued availability of Namenda IR. DSUF ¶ 425. Forest updated its website for Namenda IR and Namenda XR to include a banner message which announced the continued availability of Namenda IR in a similar manner to the website announcements of the February 2014 withdrawal. DSUF ¶ 427. Forest issued a press release regarding the injunction, which was published on various websites, in a substantially similar

form as the February 2014 announcement. DSUF ¶ 428. Forest communicated with its sales representatives and managers about the continued availability of Namenda IR. DSUF ¶ 429.

2. The Effect of the Injunction and Continued-Availability Announcements

Forest never removed Namenda IR from the market or limited its distribution in any way. DSUF ¶ 491. The NYAG confirmed that Forest complied with the injunction, that the injunction was effective in protecting competition in the relevant market, and that Forest had performed its obligation to inform the market about the injunction and the continued availability of Namenda IR "in the same or substantially similar manner in which it announced in February 2014 the potential plan to discontinue Namenda IR." DSUF ¶¶ 487-94.

"As a result of the injunction," the NYAG said, "Alzheimer's patients have not been forced to switch from Namenda IR to Namenda XR, and instead have been able to select which drug to use based on their and their physicians' views of which drug is best for them." DSUF ¶ 493. "Patients who wished to remain on Namenda IR during early 2015 and then switch to the generic version when it became available over the summer were able to do so without any disruption in their medical treatment. In addition, Alzheimer's patients who wish to take Namenda XR instead of Namenda IR are also free to do so." DSUF ¶ 494.

In July 2015, five generic manufacturers entered the market with generic Namenda IR. DSUF ¶¶ 439 (DRL), 441, (Sun), 443 (Mylan), 445 (Amneal), 447 (Lupin).

SUMMARY JUDGMENT LEGAL STANDARD

In accordance with the Court's Individual Practices and Procedures, Forest does not set forth the general standard for granting summary judgment under Federal Rule of Civil Procedure 56. In antitrust cases, "summary judgment is particularly favored because of the concern that protracted litigation will chill pro-competitive market forces." *PepsiCo, Inc. v. Coca-Cola Co.*,

315 F.3d 101, 104 (2d Cir. 2001); *see also Tops Mkts., Inc. v. Quality Mkts., Inc.*, 142 F.3d 90, 95 (2d Cir. 1998) ("By avoiding wasteful trials and preventing lengthy litigation that may have a chilling effect on pro-competitive market forces, summary judgment serves a vital function in the area of antitrust law.") (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 593-94 (1986); *Capital Imaging Assocs. v. Mohawk Valley Med. Assocs., Inc*., 996 F.2d 537, 541 (2d Cir. 1993)); *Commercial Data Servs. v. IBM*, 262 F. Supp. 2d 50, 62-63 (S.D.N.Y. 2003) (McMahon, J.).

ARGUMENT

I. DPPs Lack Record Evidence that Forest's Settlements with Generic Manufacturers Contained an Unlawful Reverse Payment

A. *FTC v. Actavis* Prohibits Only Certain Patent Settlements Involving Large and Unjustified Payments

In *FTC v. Actavis, Inc.*, the Supreme Court held that, where a large and unjustified "reverse payment"—that is, a payment from an innovator to a generic manufacturer in a patent litigation settlement—can be established, such payment can *sometimes* create the risk of anticompetitive effects. 133 S. Ct. 2223, 2227, 2237 (2013). In doing so, the Court acknowledged that patents permit a patentee to foreclose infringing competition, and that settlement is encouraged. *See id.* at 2230-31, 2234. Nonetheless, the Court held that the "unusual" situation where a reverse payment was made in order to protect a patent that the innovator perceived to be weak, rather than as a traditional form of consideration exchanged in settlement agreements, could "sometimes violate the antitrust laws." *Id.* at 2231-32. However, as the Court explained, "[w]here a reverse payment reflects traditional settlement considerations, such as *avoided litigation costs* or *fair value for services*, there is not the same concern that the patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of

noninfringement" and "[i]n such cases, the parties may have provided for a reverse payment without having sought or brought about [] anticompetitive consequences . . . ." *Id.* at 2236 (emphasis added).

The Court previously held that to "*trigger antitrust concern* under *Actavis*" DPPs must establish (1) a payment, (2) made in reverse, from the innovator to the generic, (3) that is large, and (4) that is unexplained or unjustified. *Namenda I,* at *42 (emphasis added) (citing *Actavis*, 133 S. Ct. at 2237); *see also Actos* 2015 U.S. Dist. LEXIS 127748, at *39. Other courts have agreed that for a patent settlement to even potentially come within *Actavis's* ambit, as a threshold matter, the plaintiff must establish the existence of a large and unjustified or unexplained reverse payment. *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 162-63 (3d Cir. 2017) ("*Wellbutrin II*") (only after agreements are established to include large and unexplained reverse payments are they evaluated under the rule of reason).

As noted, the existence of a "reverse" payment is not in itself unlawful. *Actavis*, 133 S. Ct. at 2237 (declining to hold reverse payments presumptively unlawful); *see also Wellbutrin II*, 868 F.3d at 160-61; *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 262 (D. Mass. 2014). Indeed, even a large and unjustified reverse payment creates only an *inference* of potential anticompetitive effects. *Actavis*, 133 S. Ct. at 2236. Therefore, in order to defeat summary judgment, DPPs must also establish the anticompetitive effects of a large and unjustified reverse payment under a rule of reason analysis. *See Namenda I*, at *42-43 (quoting *Actavis*, 133 S. Ct. at 2237); *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 754 (E.D. Pa. 2015) ("*Wellbutrin I*") (holding "plaintiffs must present a 'genuinely disputed issue of material fact' as to the elements of the rule of reason analysis; only then will the case go to the jury") (citing *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 316 & n.12 (3d Cir. 2010)).

Under the rule of reason, DPPs bear the initial burden of showing, first, there was a cognizable "reverse" payment and, if so, that the payment caused an actual anticompetitive effect. *See Namenda I*, at *43. Under this first step, plaintiffs must show that a reverse payment "exceeded anticipated future litigation costs, exceeded the costs of other services, and lacked 'any other convincing justification,'" and that it, in fact, caused delay. *Nexium*, 42 F. Supp. 3d at 262; *see also Namenda I* at *41-42; *see also In re K-Dur Antitrust Litig.*, No. 01-cv-01652-SRC-CLW, 2016 U.S. Dist. LEXIS 22982, at *44-45 (D.N.J. Feb. 25, 2016) ("[T]he burden must be on Plaintiffs to show that the settlement delayed the generic company's entry onto the market, that the brand-name company paid the generic company consideration of some kind, and that the consideration exchanged in the settlement exceeded the estimated cost of litigation and the costs of other services and products, in order to establish a prima facie case."). In assessing these matters, the analysis must be performed from the patentee's perspective because the threshold inquiry under *Actavis* is whether the patentee is sharing part of its patent-protected profits. *See Actavis*, 133 S. Ct. at 2236. The key threshold issue as to whether there is a reverse payment to begin with turns on whether any value realized by the settling generic "is something costly to the patentee"—if it is not (for example, if the patentee received as much value as it conveyed) there can be no anticompetitive concern. *See King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp. ("Lamictal")*, 791 F.3d 388, 405 (3d Cir. 2015), *cert. denied*, No. 15-1055, 2016 U.S. LEXIS 6717 (Nov. 7, 2016). [1]

[1] *See also* Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, & Carl Shapiro, *Activating Actavis*, 28 ANTITRUST 16, 18 (Fall 2013) ("Where the payment takes a form other than a simple cash transfer from the patentee to the claimed infringer, consideration should be valued from the perspective of the patentee."); Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, Carl Shapiro, *The* Actavis *Inference*, 67 RUTGERS U. L. REV. 585, 594 (2015) ("for non-cash reverse payments, the courts should seek to measure the dollar value sacrificed by the patent holder as a result of the agreement it reached with the alleged infringer"); Carl Shapiro, *Antitrust Limits to*

Only if plaintiffs meet their burden of showing (a) the existence of a cognizable reverse payment, (b) that the payment was large and unexplained, and (c) that such a payment had anticompetitive effects, do defendants then have a burden to "offer evidence" (*i.e.,* a burden of production) that the "challenged conduct promotes a sufficiently procompetitive objective." *See Wellbutrin I*, 133 F. Supp. 3d at 758; *see also United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 238 (2d Cir. 2003) (Defendants' burden under step two of the rule of reason is a "burden of production"); *Namenda I*, at *43. Plaintiffs then have the burden to show that the reverse payment was not reasonably necessary to achieve the justifications for the payment. *Wellbutrin I*, 133 F. Supp. 3d at 753; *see also Namenda I*, at *43. As in any civil case, plaintiffs bear the ultimate burden of proof.

Although prior to discovery, the Court noted that the allegation in this case that the patent litigation settlements "were intentionally designed to keep competitors out of the market *until* [Forest] had successfully forced Namenda IR consumers to switch to Namenda XR," was "idiosyncratic enough" to distinguish it from *Actavis* and Judge Abrams's decision in *Actos* to survive a motion to dismiss, (*Namenda I*, at *49-50 (emphasis in original)), discovery has yielded no evidence to support a single plan hatched in 2010. DPPs have since conceded that the decision to do the hard switch was made *at least three years after* the Mylan patent settlement, and thus could not plausibly have been the motivation for settling. Expert Report of Ernst R. Berndt, Ph.D. ("Berndt Rep.") ¶ 51; Amended Expert Report of Dr. Russell L. Lamb ("Lamb

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Patent Settlements, 34 RAND J. of Econ. 391, 408 (Summer 2003) ("if the noncash assets received by the patentholder have no well-defined market value, it becomes necessary to estimate their value to the patentholder. If the patentholder is receiving more in value, as seen through its own eyes, than it is giving up, the patentholder is making no net payment to the challenger, and there is no basis for presuming that the settlement delays entry in comparison with litigation.").

Rep. I") ¶ 89. The analysis of reverse payment allegations must thus proceed under the normal *Actavis* framework.

Summary judgment should be granted for Defendants on DPPs' reverse payment claim because DPPs cannot even make it out of the starting gate by establishing a cognizable reverse payment, let alone one that is large and unjustified, or that caused anticompetitive effects.

B. DPPs Lack Evidence of a Large and Unjustified Reverse Payment

1. Discovery Eliminated The Vast Majority of DPPs' Reverse Payment Claims

Following discovery, DPPs' case is just a sliver of their original allegations. In blunderbuss fashion, DPPs asserted that Forest entered into anticompetitive reverse payment settlement agreements with *ten* first filer generic manufacturers. First Amended Class Action Complaint (Oct. 13, 2015) ("Am. Compl."), Case No.: 15-cv-7488, Dkt. 26, at ¶¶ 114, 246. But after discovery failed to support their wide-ranging allegations, DPPs have functionally abandoned their challenge to all but one of these agreements. None of DPPs' nine experts even attempt to suggest that the settlements other than with Mylan ("Other Settlements") were anticompetitive. DSUF ¶ 145; Lamb (Oct. 6) Dep. 231:20-21; Elhauge (Sept. 29) Dep. 37:15-39:15; Elhauge (Nov. 10) Dep. 309:15-310:25. Thus, Forest's expert opinion on the propriety of the Other Settlements stands unrebutted. DSUF ¶ 145. Presumably for this reason, in DPPs' class certification briefing and proposed trial plan (filed at the close of fact discovery), DPPs make no mention whatsoever of the Other Settlements. DPPs' Mem. in Supp. of Mot. For Class Cert, Dkt. 402, at 2, 3, 4, 17, 19; DPPs' Memo. in Supp. of Mot. For Class Cert, Dkt. 402, Ex. 2, Proposed Trial Plan, at 1, 2.

Nor could DPPs successfully pursue claims that the Other Settlements contained large and unjustified reverse payments because it is undisputed that those agreements each consisted

of: (1) a license for generic entry three months before patent expiry with the possibility of acceleration, and (2) a nominal payment (from $150,000 to $2 million) reflecting a portion of Forest's avoided litigation costs and the generic's expended litigation costs.[2] DSUF ¶¶ 85, 94, 99, 104, 109, 114, 119, 125, 131. None of these terms support a claim of a large and unjustified reverse payment. *Infra* I.A. And Forest's expert opinion that the Other Settlements involved no large and unjustified payments and no possibility of delay stands unrebutted. DSUF ¶ 145. As DPPs have not even attempted to show a cognizable net reverse payment, let alone one that is large and unjustified, summary judgment should be granted as to the Other Settlements.

Similarly, while DPPs previously suggested that the Ceftaroline Term Sheet, entered into on the same day as the Orchid settlement was anticompetitive, DPPs' Opp'n to Mot. to Dismiss, Dkt. No. 69, at 26, DPPs apparently have abandoned that allegation as well. Unrebutted evidence makes clear that the Ceftaroline Term Sheet was an arm's length business transaction for fair value that required Orchid to meet specific milestones to receive payments, and that it allowed Forest to source ceftaroline API more cheaply. DSUF ¶ 179; Solomon (Sep. 7) Dep. 213:15-215:20. As such, it is not surprising that DPPs' seventeen expert reports are silent on the Ceftaroline Term Sheet, and summary judgment should be granted as to that agreement.[3]

Accordingly, the only remaining issue relates to the Mylan settlement.

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[2] Generics deposed in the case confirmed that their litigation costs exceeded the amount of the payment, and that they expected to incur additional litigation costs had they not settled. DSUF ¶¶ 85, 99, 110, 120, 126, 137.

[3] In light of the above, Defendants contacted DPPs to discuss a stipulation eliminating DPPs' contentions that the Other Settlements (or Ceftaroline Term Sheet) were anticompetitive. Despite DPPs' apparent abandonment of those issues and the lack of record evidence to support those claims, DPPs refused to streamline their case for summary judgment.

2. The Settlement Agreement with Mylan Does Not Raise Triable Factual Issues Under *Actavis*

The settlement agreement between Forest and Mylan consisted of the standard package that Forest offered to all first filers: (1) a payment for litigation costs, and (2) three months early entry with the possibility of acceleration. Neither is a suspect payment under *Actavis*.

a. Payments Below Litigation Costs Do Not Qualify As Reverse Payments

Actavis held that reverse payments reflecting traditional settlement considerations, such as payment for avoided litigation costs, do not give rise to concerns that the settlement was anticompetitive. *Actavis*, 133 S. Ct. at 2236.[4] The reason is straightforward: where a patentee would otherwise expend money to litigate, even to a successful result, it can instead use the same money to settle without incurring any form of sacrifice or net "payment"—and thus cannot be deemed to be paying to shore up what it views as a weak patent. *See Actavis*, 133 S. Ct. at 2236-37 (to be suspect, payment must be a "workable surrogate for the patent's weakness"); Elhauge (Nov. 10) Dep. 324:25-327:9 (agreement that makes economic sense on a stand-alone basis would not be reverse payment because there is no basis to infer delay).

[4] The FTC similarly agrees that payments by the innovator to the generic for avoided litigation fees of up to $7 million do not constitute an unlawful reverse payment, having now entered into stipulated orders—including two orders since the motion to dismiss briefing in this case—in at least two different cases in which it specified as much. Stipulated Order for Permanent Injunction with Endo Pharmaceuticals Inc. and Endo Int'l, Inc., *FTC v. Allergan*, No. 17-00312, ECF No. 4, at *3-4, (N.D. Cal., Jan. 23, 2017); Stipulated Order for Permanent Injunction with Teikoku Seiyaku Co., Ltd., and Teikoku Pharma USA, Inc., *FTC v. Teikoku Pharma USA, Inc.* , No. 16-01440, ECF No. 3-1, at *7, (E.D. Pa. Mar. 30, 2016); *see also* Order at 4, ¶ 21.a, *FTC v. Cephalon Inc.*, No. 08-2141 ECF No. 405 (E.D. Pa. June 17, 2015), And in the FTC's report on reverse payment agreements released this month, the FTC reported the number of settlement agreements that could "potentially involve" reverse payments, excluding settlements in which the only compensation is the payment of less than $7 million in litigation fees. FTC, *Agreements Filed with the Fed. Trade Comm'n under the Medicare Prescription Drug, Improvements, and Modernization Act of 2003*, 1 (Nov. 2017).

The $2 million payment was made to defray a portion of Mylan's already-expended litigation costs and to reflect a portion of Forest's saved litigation costs. DSUF ¶ 110; Silber (Mylan) Dep. 16:20-24. DPPs concede that this $2 million payment was well below Forest's expected future litigation costs in the absence of settlement. Revised Expert Report of Professor Einer Elhauge ("Elhauge Rep. I") ¶ 20 (adopting Mr. Johnston's estimate that "Forest would have expected future litigation costs of $3.5 million").

Because there is no genuine dispute that the $2 million payment to Mylan for litigation costs was below any estimate of Forest's avoided litigation costs, Forest is entitled to summary judgment that the $2 million payment does not qualify as a reverse payment warranting further review under *Actavis*.

b. An Agreed Early Entry Date With the Possibility of Acceleration is Not an Illegal Reverse Payments

As *Actavis* makes clear, settlements under which parties merely agree on an entry date prior to patent expiry are lawful and warrant no further scrutiny. *See Actavis*, 133 S. Ct. at 2237. Thus, there can be no question that the three months early entry provided to Mylan was lawful. Moreover, as DPPs' own economist concedes, early entry acceleration clauses cannot be viewed as reverse payments (let alone large and unjustified reverse payments for delay). Elhauge (Nov. 10) Dep. 337:4-11 (Q: "Is it your opinion that when it comes to the first filer settlers other than Mylan, that the acceleration clauses were a reverse payment?"; A: "No, I don't think so. . . ."). As Prof. Elhauge admits, the acceleration clauses simply offer "some prospect of entry even earlier than three months." *Id.* at 336:22-337:33. Prof. Elhauge also conceded that, if triggered, acceleration clauses would be procompetitive. Elhauge Rep. I ¶ 8; Elhauge (Sep. 29) Dep, 91:14-21; *see also Actos*, 2015 WL 5610752, at *15. In sum, acceleration clauses do nothing more than set a date for generic entry, and therefore simply do not warrant antitrust scrutiny

under *Actavis*. *See Actavis*, 133 S. Ct. at 2237; *see also Actos*, 2015 WL 5610752, at *16 (acceleration clauses not unlawful under *Actavis*). (The acceleration provisions also do not support an overarching conspiracy. *See infra* § III.)

3. There is No Genuine Factual Dispute that The Lexapro Amendment was a Fair Value Business Transaction, Not Cover for an Unjustified Reverse Payment for Delayed Generic Entry

The issue at the forefront of this case is whether the Lexapro Amendment disguised a payment for delayed generic entry—it did not. The Supreme Court has specifically endorsed fair value business deals entered contemporaneously with a patent settlement because fair value transactions do not raise the kinds of anticompetitive concerns raised by a large, unexplained reverse payment. *Actavis*, 133 S. Ct. at 2236. In other words, if a patentee enters a deal in which it extends value, but receives as much or more value in return, it cannot be viewed as having made the type of "payment" *Actavis* was concerned with, in which the patentee sacrificed patent protected profits. Thus, in analyzing an alleged reverse payment, the relevant antitrust question is not whether there was a contemporaneous business deal, but whether the business deal was so one-sided as to amount to such a sacrifice. *Actavis*, 133 S. Ct. at 2236-37; *see supra* I.A. Traditional settlements reflecting fair value for services thus are not "unjustified" or "unexplained" payments that give rise to antitrust concerns, as they contain no net "payment" within the meaning of *Actavis*. *Actavis*, 133 S. Ct. at 2236-37 ("Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs ***or fair value for services***, there is not the same concern that the patentee is using its monopoly profits to avoid the risk of patent invalidation.") (emphasis added). Where the patentee instead receives fair value for its payment—such that it is not "out of pocket"—the agreement cannot be viewed as anticompetitive.

As DPPs admit, whether an agreement reflects fair value is determined by the parties' expectations of fair value at the time of the agreement. *See Valley Drug Co. v. Geneva Pharm.*, 344 F.3d 1294, 1306 (11th Cir. 2003) ("the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into"); *Apotex, Inc. v. Cephalon, Inc.*, No. 2:06-cv-2768, 2017 U.S. Dist. LEXIS 87936, at *18 (E.D. Pa. June 8, 2017) (legal scholars and courts concur with the ex ante interpretation of reverse payment settlements). Experts on both side of this case agree. *See* Elhauge Rep. ¶ 12 ("[W]hat is relevant are the parties' expectations at the time of settlement."); Elhauge (Sep. 29) Dep. 129:9-19; Green Dep. 76:2-9 ("In doing any analysis of fairness, one would take a look at the expectations of the parties at the time the deal was done").

No reasonable juror could conclude that the Lexapro Amendment between Forest and Mylan was anything but an arm's length business transaction, made for fair value, based on the reasonable business expectations at the time of the agreement. Among other things, it is undisputed that by July 2009, prior to any settlement discussions, Forest began plans to approach Mylan regarding modifying the Original Lexapro Agreement due to concerns about Medicaid "best price" liability. DSUF ¶ 220; Declaration of Kristen O'Shaughnessy ("KO Decl.") Ex. 76 (July 22, 2009 Email from David Solomon ("You should let [Mylan] know that we would like to have a meeting in the fall to discuss a possible adjustment to the [Original Lexapro Agreement] deal structure. In addition to understanding the legal aspect, we should look at the potential cost of the best price issue.")).

Whereas Forest's in-house counsel negotiated the Namenda patent settlement with Mylan, a largely separate team of Forest business people negotiated the Lexapro Amendment with Mylan, as Forest would only enter such a deal if it made sense as a standalone business

deal. DSUF ¶ 275; Solomon (Nov. 15) Dep. 420:11-421:11. Indeed, the record indicates that the terms of the Namenda patent settlement had been agreed in principle in January 2010 and did not change while the business development teams continued to negotiate the Lexapro Amendment. DSUF ¶ 279.

The team negotiating the Lexapro Amendment, led by David Solomon, sought to address the expected Medicaid "best price" liability Forest would incur if it manufactured the Lexapro AG for Mylan, as was required under the Original Lexapro Agreement because the Medicaid rebate regulations had changed. DSUF ¶¶ 203-214, 220-35. Additionally, Forest long expected that Mylan would terminate the Original Lexapro Agreement after its one-year commitment and begin selling its own product without paying royalties to Forest. So Forest knew that extending Mylan's commitment to continue selling Forest's AG beyond one year would be valuable to Forest. DSUF ¶¶ 245-52.

a. It is Undisputed that Forest Estimated It Would Save More than $26 Million in Medicaid Best Price Liability by Shifting Responsibility for Manufacturing of the Lexapro AG to Mylan

DPPs concede that the Lexapro Amendment resulted in substantial Medicaid savings for Forest. Rather than rebutting the opinions of Defendants' expert on Medicaid rebate savings, DPPs' expert expressly adopts them. Rebuttal Expert Report of Professor Einer Elhauge ("Elhauge Rep. II") ¶¶ 22-23; Elhauge (Nov. 10) Dep. 262:1-9 (agreeing with Bonelli that moving manufacturing from Forest to Mylan would reduce Forest's payments to Medicaid by $22.2 million on a net present value basis). Under the Medicaid Drug Rebate Program ("MDRP"), all drug manufacturers participating in Medicaid, like Forest, are required to provide rebates to the Medicaid program on a quarterly basis for drugs dispensed to Medicaid patients. DSUF ¶¶ 197-98; Expert Report of Alexandra Mooney Bonelli, CFE ("Bonelli Rep."), Section

A. The size of the rebate owed is primarily based on the manufacturer's lowest price available to any commercial customer during the quarter (the "best price"). DSUF ¶¶ 200, 206; Elhauge (Nov. 10) Dep. 262:10-18 (agreeing with Bonelli). Originally there were no statutory requirements for the treatment of authorized generics ("AGs") in calculating the best price rebate for branded drugs. DSUF ¶ 204.

However, the Deficit Reduction Act ("DRA") Final Rule, which went into effect on October 1, 2007, altered the profitability of the Original Lexapro Agreement from Forest's perspective. DSUF ¶¶ 206, 223-26. Under the DRA Final Rule and subsequent Q&As, CMS made clear that if a brand manufacturer manufactured an AG, it would be required to report the AG price as its best price for the branded drug. Thus, under the DRA, if Forest manufactured the Lexapro AG product and supplied it to Mylan, as was required under the terms of the Original Lexapro Agreement, the new "best price" rebate for branded Lexapro would have been based on the transfer price of the significantly less expensive Lexapro AG product Forest provided to Mylan, not on the best price of Forest's brand Lexapro product. DSUF ¶¶ 207-14; Elhauge (Nov. 10) Dep. 262:19-263:3 (agreeing with Bonelli about the method for calculating best price under the Original Lexapro Agreement).

Shortly after the DRA Final Rule in 2007, Forest recognized that manufacturing AG products as required by the Original Lexapro Agreement would lead to substantial best price financial exposure for sales of brand products. DSUF ¶¶ 208, 216, 217; KO Decl. Ex. 75 (PowerPoint presentation explaining the impact of the DRA on Authorized Generics). Forest estimated that manufacturing the Lexapro AG for Mylan, under the new rules, would lead to "tens of millions of dollars in exposure" in additional best price rebates owed on branded Lexapro sales. *See* Solomon (Sept. 7) Dep. 355:2-356:14; Solomon (Nov. 15) Dep. 396:18-

397:18; Bonelli Rep. ¶¶ 30-39 ("As a result of the manufacturing and financial changes in the Lexapro Amendment, the innovator Lexapro Best Price would only reflect Forest's lowest commercially available price and this price would become the Best Price."); KO Decl. Ex. 123, ¶¶ 14-15.

Forest evaluated whether it could avoid this outcome by shifting manufacture of the Lexapro AG to Mylan, so that Forest's best price would be for branded Lexapro, not the AG transfer price to Mylan. DSUF ¶¶ 215, 222; *see also* Bonelli Rep. ¶ 37 ("It is both reasonable and plausible that a manufacturer in Forest's position would seek to amend the Original Lexapro Agreement in light of the regulatory changes to Medicaid rebate liability for AGs, which were enacted after the Original Lexapro Agreement was executed."); Elhauge (Nov. 10) Dep. 263:5-264:3 (agreeing with Bonelli that, by no longer manufacturing Lexapro AG, Forest would no longer have to include those sales in its calculation of best price). Forest created numerous iterations of a financial analysis that compared Forest's expected Medicaid liability under the Original Lexapro Agreement to Forest's expected Medicaid liability if Mylan took over manufacturing. DSUF ¶¶ 215-16, 221-22. These analyses incorporated various assumptions, including forecasts, manufacturing costs, and contract discounting, from the responsible groups at Forest, and were reviewed and relied upon by David Solomon and his team. DSUF ¶¶ 225-26. Forest forecasted that this modification would save Forest approximately $26.5 million in best price liability under the DRA. DSUF ¶¶ 234-35, 265. DPPs contest neither the fact of nor general magnitude of these savings to Forest. DSUF ¶¶ 233-35; Elhauge Rep. II ¶¶ 22-23 (analyzing, but not disputing, Mr. Green's calculation that Forest's payment to Medicaid would be $26 million lower under the Lexapro Amendment); Elhauge (Nov. 10) Dep. 262:1-9 (agreeing

that the effect of moving manufacturing from Forest to Mylan was to reduce quarterly payments made to Medicaid).

Forest and Mylan ultimately agreed under the Lexapro Amendment that Mylan would take over the responsibility of manufacturing Lexapro AG. DSUF ¶ 257. By shifting manufacturing to Mylan, the best price calculation for Forest would thus no longer be based on its lower AG transfer price. Bonelli Rep. ¶¶ 28, 29, 33, 34. During negotiations, Mylan learned that Forest would save "a significant sum" on Medicaid rebate payments by shifting manufacturing to Mylan. It follows that Mylan would seek to leverage that information to obtain additional benefits in the amendment in exchange for agreeing to take over manufacture.

b. Securing a Second Year of Expected Royalties from Mylan Provided Forest with an Expected $21.1 Million Additional Profit on Lexapro AG

Undisputed testimony confirms that Forest expected Mylan would terminate the Original Lexapro Agreement after one year, as permitted under the agreement. DSUF ¶¶ 196, 246, 249; Solomon (Nov. 15) Dep. 425:4-426:21. This expectation makes perfect sense: by terminating and launching its own generic Lexapro product under its own ANDA, Mylan would avoid having to pay the 40% royalty owed to Forest from the sale of the Lexapro AG. DSUF ¶ 240. Thus, securing Mylan's commitment to sell Forest's product for an additional year would be of substantial value to Forest. DSUF ¶¶ 246, 248, 252; Solomon (Nov. 15) Dep. 425:4-426:21. Forest's forecasts confirm this expectation, showing that Forest projected only one year of profit share payments prior to agreeing with Mylan to extend the minimum term to two years. DSUF ¶¶ 245, 247. So while DPPs' experts speculate that Mylan may not have terminated after the first year (Rebuttal Expert Report of James Bruno ("Bruno Rep. II") ¶¶ 9, 18; Elhauge Rep. II ¶¶ 3, 17-21), that is beside the point. There simply is no factual dispute that in 2009 and 2010 *it*

was Forest's expectation that Mylan would exercise its option to terminate the agreement after one year. DSUF ¶¶ 246, 249.

Accordingly, Forest and Mylan agreed to modify the agreement to require Mylan to sell the Lexapro AG for a minimum of two years and to modify the existing profit-share percentages. DSUF ¶¶ 263, 264. The revised profit-share percentage reduced the royalties Mylan owed to Forest by $12.5 million on the first $150 million of Lexapro AG product profit, but left them unchanged on any profits above $150 million. DSUF ¶¶ 242-44. But securing Mylan's commitment to a second year of Lexapro AG royalty payments provided Forest with an expected $21.1 million in additional value in year two of the amended agreement. DSUF ¶¶ 248, 250, 265. DPPs' experts—the very same experts that otherwise rely on Forest's forecasts to predict Namenda conversion—do not question the math behind Forest's forecasts, the methodology, or that the forecasts were made by Forest in the ordinary course of business by people with knowledge in their fields. Solomon (Nov. 15) Dep. 422:18-424:24. Moreover, it is undisputed that the forecasts were sent to, reviewed, and relied on by David Solomon while he and his team were negotiating the amendment with Mylan. *Id.* Rather, looking back in time, DPPs resort to questioning the reliability of the forecasts. *See, e.g.*, Berndt Dep. 205:21-206:2 ("Q. So am I correct that your testimony or criticisms with respect to Lexapro are focused on assessing the reliability of the forecasts ***that Forest relied on*** in connection with the Lexapro amendment; is that correct? . . . A. That's correct.") (emphasis added); Bruno Rep. II Section III.C.; Amended Reply Expert Report of Ernst R. Berndt, Ph.D. ("Berndt Rep. II") Section II; Elhauge Rep. II ¶ 17. In other words, DPPs are not contending (and cannot contend) that Forest did not create and rely on the Lexapro profit-share projections when Forest negotiated the Lexapro Amendment with Mylan. *See e.g.* Bruno Dep. 289:18-290:6 ("[O]bviously these [projections] were prepared,

and one would have to believe they were prepared for discussing what this deal would look like on the long and the short term.").

However, clutching at straws, DPPs now challenge the *reliability* of the profit share projections because ultimately the Lexapro AG proved not to be as successful as Forest projected it would be, due to the fact that Teva (the other generic competitor in the first 180 days post-generic launch) took a highly aggressive and unusual low pricing strategy. *See e.g.* Solomon (Nov. 15) Dep. 429:25-431:7 (explaining Teva took a more aggressive pricing position than Forest expected); KO Decl. Ex. 16 ("Apparently generic discounting has been . . . way higher than anyone would expect from two normally 'rational' generic co's in a 2-player market."). DPPs' experts of course make no effort to put forth alternative profit projections of their own. But, as discussed above, it is undisputed that the relevant question is what Forest believed at the time it entered the agreement—not second-guessing years later. DSUF ¶¶ 215, 224-27, 232, 236, 239, 246, 249, 253-54. Indeed, as DPPs' own expert explained, what ended up happening in the real world is irrelevant, and this concession ought to be dispositive of the point:

> Q. You didn't do any independent analysis to assess the reliability of the financial figures in this document. Correct, sir? . . .
>
> A. I did not. I was relying on the fact that they projected it, which is what matters. ***What matters is what they estimated, not what actually turned out to be the case***.
>
> Q. You didn't do any independent analysis to assess the reliability of the assumptions incorporated into this document. Correct?
>
> A. I did not. And, again, ***it doesn't matter whether their estimates were right or not. What matters is that they were their estimates***. ***That's what would inform their settlement***.

Elhauge (Sept. 29) Dep. 144:20-145:9 (emphasis added). Further, DPPs' expert who analyzed the forecasts did not go so far as to contend that the Lexapro forecasts Forest used were somehow a sham or created fraudulently. *See* Berndt Dep. 279:7-15 ("Q. Dr. Berndt, in your review of all the documents in this case, all the testimony in this case, and putting together your

two reports, you're not aware of a single document or a single witness testifying that the Lexapro forecasts were created as a sham or made fraudulently; correct? . . . A. I'm not making such an allegation."). DPPs have no evidence, and certainly their experts cite none, to suggest that Forest's Lexapro profit share forecasts were anything but what they appear to be—bona fide forecasts created for the purpose of negotiating the Lexapro Amendment. *See* Green Dep. 249:18-250:12. In the end, it is undisputed that the profit share forecasts (1) were created by a team at Forest who specialized in such work, (2) were refined through multiple iterations over several months while the Lexapro amendment was being negotiated, and (3) were relied on by the Forest team negotiating the amendment.

c. There is No Dispute that the Lexapro Amendment was a Legitimate, Arm's Length Business Transaction that Benefited Both Mylan and Forest

When DPPs' hindsight-driven attacks on the profit share forecasts are properly disregarded, there can be no legitimate dispute the Lexapro Amendment provided fair value to both Forest and Mylan for the benefits and services each party received. The benefits to both sides must be looked at in their totality to assess whether the parties' expectations at the time of the Lexapro Amendment represented a fair value arrangement. Elhauge (Sept. 29) Dep. 66:25-67:10 ("So the reverse payment value to the generic is the amount they receive minus any costs that they incur. The amount paid by the patent holder is the amount they pay minus any benefits they receive."). As summarized in Exhibit E of the Green Report, Forest expected to receive $26.5 million in Medicaid rebate savings and $21.1 million in additional royalties from the second year of the agreement, in exchange for the $20 million payment to Mylan and a reduction of Forest's expected profit-share by $12.5 million. Mylan received $20 million under the amendment and a royalty reduction of $12.5 million, but was also forecasted to pay an additional $31.7 million in royalties in the second year of the agreement. (Forest's benefit of $21.7 million

of profit share payments is lower than Mylan's cost of $31.7 million because Forest had to pay royalties on profits to Lundbeck, its API supplier.) In short, by modifying the Lexapro Agreement, Forest expected to obtain net benefits amounting to $15.1 million in reduced liabilities and additional cash flow. Similarly, Forest expected Mylan to obtain net benefits of approximately $800,000. Both Forest and Mylan were expected to be better off under the Lexapro Amendment.

Benefits Received (Owed)	Forest	Mylan
Lump Sum Payment at Execution of the Modification	($20.0M)	$20.0M
Impact on First Year Profit Share	($12.5M)	$12.5M
Impact on Second Year Profit Share (Difference Paid to Lundbeck)	$21.1M	($31.7M)
Medicaid Best Price Liability (Reduced Forest Rebate)	$26.5M	n/a
Net Benefits	**$15.1M**	**$0.8M**

Green Rep., ¶ 75.

Further, under a net present value ("NPV") analysis, which adjusts incremental cash flows for the time value of money, the NPV benefits from the Lexapro Amendment were $7.2 million each to Forest and Mylan. Green Rep. ¶¶ 79-82; Green Dep. 208:21-209:12; 220:2-24.5. While DPPs' experts try to argue that certain benefits associated with the Amendment should not be credited in a fair value analysis, none of those experts question (nor can they) the actual calculations Mr. Green employed to confirm that that the Lexapro Amendment was beneficial to both Forest and Mylan. Elhauge Rep. II ¶¶ 22-23; Elhauge (Nov. 10) Dep. 262:1-263:3; DSUF ¶ 217.

[5] Mr. Green used a 10% discount rate, which DPPs' expert agrees is appropriate. Elhauge Rep. I, ¶ 11, at 6.

Net Present Value of the Lexapro Amendment		
As of July 21, 2010	**Forest**	**Mylan**
Net Benefits	$15.1M	$0.8M
NPV of Net Benefits (10% Discount Rate)	$7.2M	$7.2M

Green Report, ¶ 79.

The Court, however, need not analyze the fair value of the Lexapro Amendment down to the dollar as Mr. Green did. On this record, there simply is no dispute that Forest had legitimate business justifications for modifying the Original Lexapro Agreement, and courts have long "recognized that firms must have broad discretion to make decisions based on their judgments of what is best for them and that business judgments should not be second-guessed even where the evidence concerning the rationality of the challenged activities might be subject to reasonable dispute." *7-UP Bottling Co. v. Archer Daniels Midland Co. (In re Citric Acid Litig.)*, 191 F.3d 1090, 1101 (9th Cir. 1999); *see also Verizon Comm'n Inc. v. Law Offices of Curtis V. Trinko*, LLP, 540 U.S. 398, 415-16 (2004) ("The Sherman Act . . . does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition.").

Finally, while Forest does not dispute that the settlement agreement and Lexapro Amendment were executed on the same day, and certain personnel had awareness of both agreements, there must be evidence to support an inference that a contemporaneous business deal was a payment for delayed generic entry in the settlement. *Actavis* teaches that such an inference can arise if the business deal is not a fair value exchange; where, as here, the evidence shows a fair value agreement, there is no basis for such an inference and summary judgment must be

granted. 133 S. Ct. at 2236. Business deals must be analyzed separately to determine whether they involved payment over fair value. *FTC v. Abbvie*, 107 F. Supp. 3d 428, 437 (E.D. Pa. 2015). If, as is the case here, the business agreement was a win-win, arm's length, fair value deal, there is nothing nefarious in the fact that the transactions were executed on the same day. It is telling in this context that DPPs have abandoned any allegations related to the Ceftaroline Term Sheet with Orchid, even though it was entered into on the same day as the patent settlement agreement between the parties. Elhauge (Nov. 10) Dep. 328:11-330:3. Apparently, DPPs agree that entering into a business deal simultaneous with a settlement agreement is not alone enough to raise a triable issue.

Summary judgment for Forest therefore should be granted because it is indisputable on this record that the financial terms of the Lexapro Amendment were commercially reasonable, and that the Lexapro Amendment constituted an arm's length business transaction in which both parties received fair value, based on their expectations at the time. *See Actavis*, 133 S. Ct. at 2236-37 (holding that the likelihood of finding anticompetitive effects from a reverse payment depends on facts such as "independence from other services for which it might represent payment, and the lack of any other convincing justification").

4. Value Transferred to Mylan Associated with Mylan Releasing A Threatened Antitrust Lawsuit Does Not Constitute a Reverse Payment

Forest received additional value in the settlement because Mylan released Forest from a threatened antitrust lawsuit. Prior to the execution of the Lexapro Amendment and Namenda patent settlement agreement with Mylan, Mylan drafted, but did not file, a draft antitrust complaint challenging conduct related to the Namenda IR patent-term extension ("PTE"). DSUF ¶ 268. Mylan sent Forest a draft antitrust complaint on February 19, 2010, at the same time the parties were in the process of negotiating the Namenda settlement. DSUF ¶ 267. As part of the

settlement, Mylan released the antitrust claims. DSUF ¶ 271. There is no dispute that, if successful, the antitrust suit, would have exposed Forest to mandatory treble damages. *See e.g.* Silber (Mylan) Dep. 20:8-16 ("Q. Mylan was seeking treble damages in this draft complaint. Correct? (…) A. Yes, I see that provision. Q. If filed and successful, the complaint could have exposed Forest to hundreds of millions of dollars of damages. Correct? A. Yes, I believe that's an accurate statement."). Courts similarly recognize—and this case certainly attests to the fact—that antitrust cases in particular are incredibly costly and time-consuming. *E.g., Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007). There is also no question that, if not settled, the antitrust claim would have exposed Forest to additional litigation costs that were avoided by the settlement. The value of such saved costs further establishes the fair value nature of the overall settlement. *See* DSUF ¶ 270; Silber (Mylan) Dep. 20:13-24.

Moreover, any payment to settle the antitrust claim must be deducted from the payments that Forest made to Mylan in determining whether a large and unjustified payment was made. The reason for this is simple: if a company facing the threat of damages pays to settle the claim, such a payment is not "reverse," but a "traditional settlement" that is explicitly carved out from possible scrutiny under *Actavis*. 133 S. Ct. at 2233 ("commonplace" settlements, including those involving the compromise of a damages claim "have not been thought for that reason alone subject to antitrust liability," and "we agree, and do not intend to alter that understanding."). Such was undisputedly a component of the settlement here. Among other things, Mylan's corporate representative testified that, from Mylan's perspective, part of the $20 million upfront payment Forest made to Mylan was to resolve the threatened antitrust complaint. DSUF ¶ 273; *see also* Silber (Mylan) Dep. 84:4-10 ("The Lexapro agreement provided compensation to Mylan for the antitrust claim they had asserted against Forest, and patent settlement agreement released

that claim."). In sum, any alleged "payment" to Mylan that was attributable to resolving the threatened antitrust complaint cannot be viewed as a "reverse payment" under *Actavis*. 133 S. Ct. at 2233.

5. No Reasonable Juror Could Find Forest Made a "Large" Reverse Payment

Even if there were some payment—and as shown above there was not—DPPs cannot plausibly argue that the payment to Mylan was "large." Under *Actavis*, the size of a reverse payment is determined from the perspective of what the innovator is sacrificing, which a court may use to infer the possibility that the innovator may have viewed its patent as weak. *See Actavis*, 133 S. Ct. at 2236-37 (the size of the reverse payment may indicate the *innovator's perception of the patent's weakness*); *id.* at 2237 (considering the scale of reverse payment in relation to the *innovator's future litigation costs*); *id.* at 2236 (concern with reverse payment is innovator sharing the *innovator's monopoly profits* to avoid risk of patent invalidation); *id.* at 2236 (the size of a reverse payment may indicate the *innovator's market power* to "recoup" its payment); *see also Lamictal*, 791 F.3d at 405 (asking whether "the source of the benefit to the claimed infringer is something costly to the patentee"); *supra* n.1. Moreover, in determining whether a reverse payment is "large," one must assess the increment by which a payment exceeds fair value and avoided litigation costs. *See, e.g.*, *Actavis*, 133 S. Ct. at 2236-37 (where payment for fair value or avoided litigation costs, no antitrust concern); *see also* Elhauge (Sep. 29) Dep. 66:2-10 ("Q: … [Y]ou looked at actual benefits paid and actual benefits received[?] … A. I looked at … the benefits paid minus the extra cost.").

And as is clear from *Actavis*, the Court's concern with reverse payments was the possibility that the innovator was unlawfully maintaining and sharing the innovator's patent-generated profits through the settlement. *Actavis*, 133 S. Ct. at 2237. Therefore, a "large"

payment from the innovator to the generic must be large in relation to the patent-generated profits allegedly protected by the settlement. *See id*. ("the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the *payor's* anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification") (emphasis added).

As shown above, the only payment from Forest to Mylan under the settlement agreement was $2 million for litigation costs. DPPs' expert opined that Forest's expected remaining profits on Namenda IR at the time of the settlement with Mylan were $2.33 billion. Elhauge Rep. I, ¶22 Tbl. 1. Assuming, arguendo, that the $2 million payment was an actionable reverse payment, it is a microscopic 0.09% (nine one-hundredths of a percent) of the alleged remaining value of the patent. Even if DPPs' allegations were credited across-the-board that Forest paid Mylan $30.9 million above fair value to settle the patent litigation—and they should not be credited, as discussed *supra*—such payment would represent 1.32% of the remaining value of the patent. Under either analysis, the payment is patently small and certainly cannot be used as a proxy for Forest's lack of confidence in its patent case. On the contrary, such miniscule numbers convey Forest's confidence in the patent litigation's outcome. Neither payment comes close to anything that the jury could determine was a "large" payment. Thus, there is no material issue of fact on the issue of whether any payment to Mylan was "large," and summary judgment should be granted for Defendants on this basis alone.

C. DPPs Cannot Establish Anticompetitive Effects Under the Rule of Reason Because No Large and Unjustified Reverse Payment Caused Delayed Generic Namenda Entry

While the above shortcomings alone support summary judgment, summary judgment is warranted for the additional reason that there is no evidence that a reverse payment *in fact*

delayed generic memantine entry. As the Court held, "[t]o survive a motion for summary judgment, Plaintiffs will have to substantiate [their] allegations [regarding the patent settlement agreements] with evidence suggesting that the settlement agreements did, in fact, *delay generic entry*." *Namenda I*, at * 51 (emphasis added). *Wellbutrin* similarly acknowledged that "the operative question [in reverse payment antitrust cases] is the manner in which the agreement – inclusive of the reverse payment – *altered the date* at which generic entry otherwise would have occurred." *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 756-57 (E.D. Pa. 2015) (emphasis added) (*aff'd In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132 (3d Cir. 2017)).

There is not a scintilla of evidence that either the payment for avoided litigation costs or the value Mylan received in the Lexapro Amendment altered the date of generic memantine entry. To the contrary, the Forest executives responsible for negotiating the Namenda patent litigation confirmed that Forest never offered nor entertained any possibility that it would agree to generic memantine entry any earlier than three months prior to patent expiration (including regulatory exclusivities). Ryan (Nov. 7) Dep. 367:12-370:2, 394:21-395:2 (a settlement agreement containing a 2012 launch date would not have been feasible or acceptable to Forest); Ryan (Sept. 7) Dep. 208:1-209:9 ("just as [the generics] wanted [acceleration clauses], we had decided that the three-month early entry is what we were willing to offer"); Agovino Dep. 75:19-76:6 ("Q. How did it come about that all . . . first filers had the same three month prior to patent expiration launch date? A. That's all Forest would agree to."); Silber (Mylan) Dep. 38:9-20 (between the time Forest offered a settlement of three months early entry, and the final settlement, the early entry date never changed); DSUF ¶ 331. Indeed, the attorney responsible for negotiating the Lexapro Amendment on Mylan's behalf—who was also deposed as Mylan's corporate witness—testified that the terms of Mylan's Namenda patent litigation settlement

agreement (including the generic entry date) were actually already set prior to the negotiation of the Lexapro Amendment. *See* Silber (Mylan) Dep. 26:5-17. In particular, he testified that the entry date was "non-negotiable." Silber (Mylan) Dep. 26:5-11. At no point did the parties discuss any other entry date. Silber (Mylan) Dep. 24:8-10 (Q: "Did Mylan and Forest negotiate over how early the entry date would be?"; A: "No, there were no such negotiations.").

Similarly, Forest's Chief Intellectual Property Counsel overseeing the litigation testified:

> [W]e had a very strong case. We were prepared to go to trial. We weren't going to give more than three months to anyone, including Mylan. So if Mylan wanted to go to trial, we could do that. . . . I was intimately involved in this case, so I advised senior management that if we could settle, and by the way, we had multiple generics right after the Markman hearing wanting to settle because they recognized that they had a thoroughly vetted patent that had been reviewed in reexamination, had two—a magistrate judge, who is now a federal district court judge, write a comprehensive Markman opinion, gave us a very strong ruling, and we were prepared to go to trial.

Ryan (Nov. 7) Dep. 366:20-368:17.

Nor can a settlement be condemned simply because a more procompetitive one can be posited: "*Actavis* requires only that a brand manufacturer not unlawfully restrict competition; it does not demand that the brand maximize competition." *Actos*, 2015 U.S. Dist. LEXIS 127748, at *50 (citing *Lamictal*, 791 F.3d at 409).

In short, there is no evidence that the parties would have arrived at an earlier entry date in a but-for world. The undisputed evidence establishes the contrary—that Forest steadfastly offered all generics three months early entry. With no evidence of delay, there can be no anticompetitive effects, and summary judgment is appropriate for this independent reason.

II. Forest Is Entitled to Summary Judgment Because DPPs Cannot Carry Their Burden on Causation, An Essential Element of Their Case

Summary judgment is proper when a plaintiff cannot raise a legitimate dispute to support its theory of causation in fact. *See, e.g.*, *Lotes Co. v. Hon Hai Precision Indus. Co.*, 753 F.3d

395, 415 n.8 (2d Cir. 2014) ("[L]ack of causation in fact is fatal to the merits of any antitrust claim.") (quoting *Argus Inc. v. Eastman Kodak Co.*, 801 F.2d 38, 41 (2d Cir. 1986)); *Lavaho, LLC v. Apple, Inc.*, 232 F. Supp. 3d 513, 529 (S.D.N.Y. 2016) (plaintiff bears burden of proving causation); *Abbey House Media, Inc. v. Apple Inc.*, 2016 U.S. Dist. LEXIS 7765, at *26 (S.D.N.Y. Jan. 22, 2016). To succeed in an action under Section 4 of the Clayton Act, DPPs must show not only that they suffered an antitrust injury, but also that the allegedly anticompetitive conduct was both the actual and proximate cause of their antitrust injury. 15 U.S.C. § 15(a) (private antitrust plaintiffs must show that their injuries were caused "by reason of" anticompetitive conduct); *Associated Gen. Contractors v. Cal. State Council of Carpenters*, 459 U.S. 519, 520 (1983); *In re Wellbutrin XL Antitrust Litig.* 133 F. Supp. 3d 734, 762-63 (E.D. Pa. 2015) (explaining that antitrust injury cannot be presumed because of the "Clayton Act's strict causation requirement.").

DPPs alleged in their complaint that earlier generic entry *would have occurred* through generics: (1) entering into alternate settlement agreements without any reverse payment, (2) prevailing in the patent litigation, (3) ignoring the pediatric exclusivity earned by Forest and launching in April 2015 in contravention of their license agreements, or (4) launching "at-risk" prior to the end of patent litigation. *See* Am. Compl. ¶ 14. But none of these allegations panned out in discovery, and DPPs lack evidence to establish antitrust causation on any of these theories. DPPs have since conceded that there was no likelihood of Mylan launching at risk.[6] Elhauge Report I, ¶ 19; Elhauge (Sept. 29) Dep. 86:21-87:6, Elhauge (Nov.10) Dep. 301:20-23. DPPs'

[6] DPPs have not pursued any arguments that generics other than Mylan would have launched at risk, which is unsurprising given the unanimous testimony by generics that they would not have done so. DSUF ¶¶ 318-327.

lack of support for a but-for world based on an alternative settlement, Mylan winning the patent case, or disregard of pediatric exclusivity are discussed in the subsections that follow.

A. DPPs' Theory of an Alternative Settlement Entry Date is Utterly Speculative And Contradicted By the Undisputed Factual Record

To withstand summary judgment, DPPs must point to evidence, not speculation, raising a triable issue that but for the allegedly anticompetitive agreement, Mylan would have launched its generic Namenda product earlier. *Wellbutrin II*, 868 F.3d at 166; *Argus, Inc. v. Kodak Co.*, 801 F.2d 38, 41 (2d Cir. 1986) ("[A]n essential element in plaintiffs' claim is that the injuries alleged would not have occurred *but for* Kodak's antitrust violation."). Where plaintiffs argue that there would have been an alternative settlement agreement allowing earlier generic entry, they must present evidence from which a reasonable jury could conclude that it is more likely than not that the alternative agreement *would* have happened: showing that the alternative agreement *may* have happened simply does not satisfy their burden. *Wellbutrin II*, 868 F.3d at 167. "[A] plaintiff cannot satisfy the summary judgment burden [on causation] based on speculation alone." *Id*.

Yet, speculation is all that DPPs advance here. DPPs' expert, Prof. Elhauge, asserts that a hypothetical alternative "no payment settlement" agreement between Forest and Mylan allowing for Mylan's generic entry on November 2, 2012 was "feasible." But there is not one iota of evidence that the parties ever *would have* entered into such an agreement, or considered such a settlement feasible or acceptable: on the contrary, the evidence shows that Forest would *not* have agreed to a settlement allowing generic Namenda entry in November 2012. Forest's Chief Intellectual Property Counsel responsible for overseeing the Namenda patent litigation at the time of the settlement testified that a settlement agreement with Mylan allowing generic entry in 2012 would have been neither feasible nor acceptable to Forest. Ryan (Nov. 7) Dep. 394:21-

395:4 ("Q: Would a settlement with Mylan that contained a launch date in 2012 have been a feasible settlement? A: No. . . . Q: Would a settlement agreement with Mylan that contained a launch date in 2012 have been acceptable to Forest? A: No."); *see also* Solomon (Nov. 15) Dep. 421:12-422:6 ("[W]ould a settlement with Mylan that had a launch date in 2012 have been acceptable to Forest? … A: We wouldn't have considered that at all."). In fact, the undisputed testimony from both Forest and Mylan witnesses is that Forest was unwilling to offer an entry date earlier than the three months early entry provided in the Other Settlements. Agovino Dep. 75:6-76:20; Ryan (Sep. 7) Dep. 199:9-200:15; Silber (Mylan) Dep. 24:8-25:20; *see also* DSUF ¶¶ 331, 332 (citing Forest internal document KE00000169 from August 11, 2009 stating that Forest would be unwilling to allow any first filer to launch more than three months before patent expiry). Nor did Forest and Mylan ever even attempt to negotiate a potential earlier generic launch date. DSUF ¶ 332; Silber (Mylan) Dep. 24:8-25:20.

In *Wellbutrin I*, the court rejected plaintiffs' claim that an alternative settlement (without a so-called "no-AG" term) could have been reached where the summary judgment record showed that Teva "expressly and unwaveringly refused to settle" without the no-AG term. *Wellbutrin I*, 133 F. Supp. 3d at 757. The fact that every draft of the settlement included the no-AG term was further evidence that an alternative settlement without the no-AG clause would *not* have been reached. *Id*. As in *Wellbutrin I*, there is no factual evidence here to support an alternative settlement with an earlier entry date—particularly a date more than two and a half years earlier than the date agreed to by every other first filer. Rather, Forest "expressly and unwaveringly refused to settle" on terms that allowed generics to enter the market earlier.

It is therefore unsurprising that in forming his opinion that an alternative agreement with generic entry in November 2, 2012 was "feasible," Prof. Elhauge did not bother to read or rely

on any of the testimony from the actual negotiators of the Forest-Mylan settlement. Elhauge (Sept. 29) Dep. 59:22-60:1 ("Q: [You did not rely on any] testimony from the actual negotiators or reliance on any documents that they wrote about the settlement. Correct, sir? A: That's right. **That's not the basis for my but-for entry date**.") (emphasis added). In fact, he confirmed that he was unaware of any evidence that Forest and Mylan ever discussed a generic entry date in November 2012, or what he calls a "no payment settlement." Elhauge (Sept. 29) Dep. 58:7-21. Prior to offering his opinions about the purported but-for entry date, he did not even know the identities of people who negotiated the settlement for Forest and Mylan. Elhauge (Sep. 29) Dep. 36:11-23. Tellingly, Prof. Elhauge posited that the record evidence that Forest insisted on the entry date that was in fact agreed upon *is not relevant* to his but-for entry date. Elhauge (Sept. 29) Dep. 73:2-8 ("Q: Are you aware that Charles Ryan testified that three months early entry was insisted on by Forest? . . . A: I'm not aware of evidence I would characterize that way, nor does it sound relevant to the but-for world.").

Prof. Elhauge's opinion, untethered to the evidence in the case, cannot create a genuine issue of fact. *See Raskin v. Wyatt Co.*, 125 F.3d 55, 66 (2d Cir. 1997) ("[A]n expert's report is not a talisman against summary judgment."). Indeed, as the Supreme Court made clear in *Brooke Group*, "expert testimony without a factual foundation cannot defeat a motion for summary judgment." *Virgin Atl. Airways Ltd. v. British Airways plc*, 69 F. Supp. 2d 571, 579 (S.D.N.Y. 1999) (citing *Brooke Grp. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993), aff'd *Virgin Atl. Airways v. British Airways Plc,* 257 F.3d 256 (2d Cir. 2001); *see also Brooke Grp.*, 509 U.S. 209 at 242 ("If an expert opinion is not supported by sufficient facts to validate it in the eyes of the law, or when indisputable record facts contradict or otherwise render the opinion unreasonable, it cannot support a jury's verdict."); *Major League Baseball Props.,*

Inc. v. Salvino, Inc., 542 F.3d 290, 311 (2d Cir. 2008) ("An expert's opinions that are without factual basis . . . [are] inappropriate material for consideration on a motion for summary judgment"); *Ortho Diagnostic Sys. v. Abbott Labs.*, 920 F. Supp. 455, 471 (S.D.N.Y. 1996) (plaintiffs could not survive summary judgment by resting upon economic theories that lack a factual foundation in the record).

Moreover, Prof. Elhauge's opinion—that an alternative "no payment settlement" allowing generic entry on November 2, 2012 was "feasible"—turns on his erroneous assumption that *any payment* from the innovator to the generic in a patent settlement agreement, even one below avoided litigation costs or fair value, causes delayed generic entry. Elhauge (Sep. 29) Dep. 79:23-80:17. But this conclusion directly contravenes *Actavis*, which allows payment for avoided litigation costs and fair value for services. *See* I.A. *supra*. Indeed, Prof. Elhauge admitted that a settlement in which Forest made a payment to Mylan equal to Forest's saved litigation costs would be *more economically rational* than his "no payment settlement" alternative. Elhauge (Nov. 10) Dep. 341:16-342:3. In other words, when allowing for settlements expressly permitted by *Actavis*, Prof. Elhauge's own conclusion is that his hypothesized November 2, 2012 alternative generic entry date would not have occurred.

Even if Prof. Elhauge's opinion is not stricken (as it should be), his speculation regarding "feasible" settlements cannot create a genuine issue of fact that Mylan *would have* entered earlier under an alternative settlement agreement, let alone that it would have been on November 2, 2012. Memo. in Supp. of Mot. to Exclude Ops. of Prof. Elhauge ("Elhauge Daubert"). *See Maxon Hyundai Mazda v. Carfax, Inc.*, No. 13-2680, 2016 U.S. Dist. LEXIS 171418, at *77 (S.D.N.Y. Sept. 30, 2016) (holding plaintiffs' unreasonable expert opinion could not defeat summary judgment and noting that "the fact that expert testimony is admissible . . . does not

necessarily entail that it will create a fact issue") (quoting Areeda & Hovenkamp, *Antitrust Law* ¶ 309(c)(2) (4th ed. 2014).

B. DPPs Cannot Establish Causation and Antitrust Injury by Reference to a Hypothetical Patent Trial Between Forest and Mylan

DPPs' alternative but-for world—that absent the allegedly large and unjustified payment Mylan would have prevailed at trial on the '703 patent—is equally speculative and does not raise a triable issue. No trial in this case is necessary to appreciate that the patent court's claim construction decisions led every generic defendant but Mylan to flee the case and settle on terms highly favorable to Forest, objectively showing that Forest's patent was unlikely to fall. And as the only remaining challenger, Mylan's apparent plan for trial was to push competing and inconsistent theories of its case, based on arguments suffering from glaring deficiencies and on evidence that the PTO had already considered before reaffirming the '703 patent in reexamination proceedings. No reasonable jury that pieced together this hypothetical patent trial could conclude that Mylan would have prevailed.

Claim construction often ends parties' disputes on the issue of infringement and is frequently case-dispositive. *E.g.*, *Scripps Research Inst. v. Illumina, Inc.*, No. 16-cv-661, 2017 U.S. Dist. LEXIS 57740, at *11 (S.D. Cal. Apr. 14, 2017) ("[Claim] constructions could be case dispositive at the outset, determining whether a plaintiff can legally state a claim for relief . . .").

There is no dispute that Judge Stark and Sleet's claim construction decisions adopted Forest's positions almost entirely; the court rejected every single claim construction proposed by the generics. DSUF ¶¶ 287-92. Most notably, Judge Stark and Judge Sleet rejected the generics' attempt to re-frame the '703 patent as covering the treatment of stroke, rather than Alzheimer's Disease, dooming the generics' strategic bid to prevail on infringement through claim construction. DSUF ¶¶ 289-292.

The subsequent flurry of settlements is also undeniable. Within months of the claim construction decision, every single generic remaining in the consolidated case other than Mylan had either settled with Forest or withdrawn its ANDA. DSUF ¶¶ 294-296. Having been transferred to the District of New Jersey, Orchid settled soon thereafter. DSUF ¶ 295. This timing was no coincidence; the Forest employees involved in settlement negotiations testified that the generic companies began asking Forest about settlement in earnest shortly after the first Markman decision. DSUF ¶ 294. And the terms of the settlements indisputably favored Forest—each generic agreed to a patent license taking effect on January 11, 2015, over five years into the future and just three months before the '703 patent was to expire, thus securing to Forest nearly all of its remaining patent term.[7] DSUF ¶¶ 83, 89, 93, 97, 103, 108, 113, 118, 124, 130, 135, 294. And as discussed, *supra* § I.B., none of the Other Settlements included any cash payments beyond modest reimbursements for litigation costs. DSUF ¶¶ 84-85, 94, 98, 104, 109, 114, 119, 125, 131, 136, 176, 278. Indeed, as noted above, DPPs have all but conceded that all settlements other than Mylan were legal.

Per *Actavis*, "the size of the unexplained reverse payment can provide a workable surrogate for the patent's weakness." *Actavis*, 133 S. Ct. at 2236-37. Here, it is undisputed that the Other Settlements involved *no* large unexplained payments. They therefore indicate that Forest's patent was strong. In other words, the generic companies' acquiescence to the strength of Forest's patent after their defeat on claim construction, without receiving any large cash payment or other improper inducement in return, is strong objective evidence of the strength of

[7] Forest's settlements with the generic defendants licensed them to begin selling generic memantine on January 11, 2015, three months before the '703 patent was to expire on April 11, 2015, *unless* Forest obtained pediatric exclusivity for Namenda®, in which case the generics were authorized to enter on July 11, 2015, three months before Forest's six-month pediatric exclusivity period would expire on October 11, 2015. DSUF ¶ 294. Forest eventually obtained pediatric exclusivity, moving the entry date to July 11, 2015.

the '703 patent and Forest's patent infringement case as a whole. Indeed, DPPs' own expert concedes that the terms of the actual settlement agreement that Forest and Mylan entered into are consistent with Forest's believing it that it had an *extremely high*—up to 94.9%—likelihood of success in the patent suit. DSUF ¶ 294; *see also* Dkt No. 238 at 12 (DPPs conceding that "[t]he settlement entry dates are consistent with Forest having a 95% chance of winning the patent cases.").

DPPs try to explain away this objective evidence by suggesting that all the generic settlers knew the '703 patent was vulnerable but nonetheless gave up because they did not truly care to launch their generic products as soon as they could, perhaps due to allegedly small projected profit margins. *See e.g.* DSUF ¶ 318. No reasonable jury could accept the argument that these generic companies—their business model being challenging patents to get to market as early as possible—readily agreed to stay off the market for virtually the entire patent term, despite allegedly believing that the patent was invalid or not infringed. Moreover, DPPs' argument is a non-sequitur—even if the generic companies did give up on litigating because their expected profits were small, that would not undermine the strength of Forest's patent in any way. On the contrary, small generic profits would serve as yet another real-world, objective justification for all the generics' decision to settle (Mylan included) that is entirely divorced from any improper sharing of monopoly profits by Forest to avoid an invalidation of its patent. And DPPs' small-profits theory certainly does not explain the *timing* of those settlements, nearly all of which followed soon after Forest prevailed on claim construction, suggesting that the generics appreciated the weakness of their case and that that understanding prompted their willingness to exit litigation.

In the face of the overwhelming objective evidence that Forest had a very strong patent case—including the reexamination to which the '703 patent was subjected prior to litigation, the presumption of validity attaching to all issued U.S. patents, and the successful claim construction rulings with the vast majority of generics settling soon thereafter— Plaintiffs allege:

> The generic defenses asserting that the claims of the '703 Patent were anticipated and obvious in view of the prior art and that Forest improperly sought and obtained a longer patent term extension than that to which it was entitled, among others, were strong. . . . In addition, one or more of the generic challengers advanced non-infringement defenses that posed additional risk to Forest. Forest was aware that the '703 Patent was weak . . . .

Am. Compl. ¶ 109. Not so. On the contrary, Plaintiffs dramatically overstate the strength of the generics' defenses.

First, the PTO already considered whether "the claims of the '703 Patent were anticipated and obvious in view of the prior art" during the reexamination proceedings before concluding that the claims were, in fact, patentable. DSUF ¶¶ 14-18. In fact, Mylan based its anticipation and obviousness arguments on prior art that the PTO *had already considered and dismissed.* DSUF ¶¶ 14, 18, 305, 308. This would have made it especially difficult for Mylan to overcome the statutory presumption of patent validity and convince the court—by clear and convincing evidence—that the same prior art rendered the claims invalid. *Tokai Corp. v. Easton Enters*., 632 F.3d 1358, 1367 (Fed. Cir. 2011) ("[A] party challenging validity shoulders an enhanced burden if the invalidity argument relies on the same prior art considered during examination by the U.S. Patent and Trademark Office."); *PowerOasis, Inc. v. T-Mobile USA, Inc*., 522 F.3d 1299, 1304 (Fed. Cir. 2008) ("When no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job. . . .") (quoting *Am. Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1360 (Fed. Cir. 1984)).

As for the generic challengers' non-infringement defenses, the patent court had already rejected their bid to win non-infringement during claim construction by limiting the '703 patent's claims to treatment of "acute interruption of blood supply to the brain," i.e., stroke. DSUF ¶¶ 282-89. As explained *supra*, virtually all of the generic defendants then gave up, apparently viewing infringement as already decided against them. DSUF ¶¶ 293-95. Only Mylan soldiered on with an implausible non-infringement defense: that its product would not, in fact, work as an NMDA receptor antagonist in patients. Mylan took this position despite (a) its own repeated statements to the FDA that memantine is an NMDA receptor antagonist, (b) its admission in an interrogatory response that "the mechanism of action by which memantine works is that of an NMDA receptor antagonism," and (c) the broad consensus in the medical community that memantine works via NMDA receptor antagonism. DSUF ¶¶ 301-03. Forest would have had no trouble proving infringement by a preponderance of the evidence.

Mylan's PTE defense was similarly implausible. The PTE statute contains a specific provision requiring a third party petition, leading to an FDA determination of a lack of diligence, before a PTE applicant's extension can be cut short. 35 U.S.C § 156(c)(1) (requiring FDA to subtract from the regulatory review period "any period *determined under subsection (d)(2)(B)* during which the applicant . . . did not act with due diligence") (emphasis added); 35 U.S.C § 156(d)(2)(b) (defining the third party petition process for determining a lack of due diligence). It is undisputed that neither Mylan nor any other party filed any such petition here. DSUF ¶ 36. As a matter of law, therefore, there was no lack of diligence for Forest to report.

In sum, Plaintiffs ask this Court to re-write history and speculate both that Mylan somehow would have prevailed in a patent trial that never occurred and that Forest knew this all along. Am. Compl. ¶ 109 ("Forest was aware that the '703 Patent was weak . . . ."). But the

objective evidence indicates that it was the generics' case that was "weak," and there is no evidence that Forest held any other view. On the contrary, Forest's Chief Intellectual Property Counsel testified that "we had a very strong case." *See supra* § I.C.

C. That Forest Accounted For Its Earned Pediatric Exclusivity In Settling Patent Litigation Is Not Anticompetitive Conduct That Delayed Generic Entry

DPPs previously moved for summary judgment that the pediatric exclusivity provisions in Forest's settlement agreements with Mylan and the other generic defendants were *per se* unlawful. Dkt. No. 138. In denying that motion, the Court explained that the provisions in the settlement agreements were, "in the truest sense, a compromise" because Forest "avoided the risk of the patent's being declared invalid, which would have allowed generic competition to start immediately," while "the Generic Competitors avoided the risk of Defendants winning . . . which would have kept them out of the market until April 11, 2015, or possibly October 11, 2015" if Forest obtained pediatric exclusivity (which it did). *In re Namenda Direct Purchaser Antitrust Litig.*, No. 15-cv-7488, 2017 U.S. Dist. LEXIS 83446, at *58 (S.D.N.Y. May 23, 2017) ("*Namenda II*"). The Court concluded that DPPs' ability to show that the pediatric exclusivity provision is anticompetitive "will depend on the presence of 'evidence suggesting that the settlement agreements did, in fact, delay generic entry.'" *Id.* at *61. Accordingly, DPPs' pediatric exclusivity allegation rises or falls on the issue of whether there was a large and unjustified reverse payment in the settlement agreements that caused delay (and if so, whether that payment led to net anticompetitive effects under a rule of reason analysis). As the settlement agreements contained no large and unjustified reverse payments that caused delay (*supra* § I), DPPs cannot meet their burden of showing that the settlement agreements containing pediatric exclusivity provisions caused antitrust injury.

III. There is No Triable Issue Of Fact Related to DPPs' Overarching Conspiracy Claim

DPPs allege that by executing a series of bilateral agreements with the first filers that had similar terms (and in particular, Generic Entry Acceleration Clauses), Forest and the first filers collectively allocated the market for memantine products to Forest. Am. Compl. ¶¶ 121, 260-61. In effect, DPPs allege a "hub and spoke" conspiracy. *See Pepsico*, 315 F.3d at 110-111. But, there is no evidence to support a finding of a single overarching conspiracy with Forest as the hub. And the post-*Actavis* case law has uniformly rejected hub and spoke conspiracy liability on very similar facts. *See Actos*, 2015 U.S. Dist. LEXIS 127748, at *74, *77-78 (holding plaintiffs' claim of conspiracy through use of Generic Entry Acceleration Clauses "fails as a matter of law"); *King Drug of Co. of Florence v. Cephalon, Inc.*, No. 2:06-cv-1797, 2014 U.S. Dist. LEXIS 84818, at *32 (E.D. Pa. June 23, 2014) (rejecting nearly identical conspiracy claim); *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 56 (1st Cir. 2016) (plaintiffs' conspiracy claims based on Generic Entry Acceleration Clauses failed as a matter of law).

A. Without Proof Of Collective Action Among Forest and All of the Generics, DPPs Do Not Have a Triable Issue

While Forest does not, of course, deny that it reached bilateral agreements with each settling first filing generic, in order to prove the existence of a hub and spoke conspiracy, DPPs must prove Forest facilitated a set of coordinated unlawful agreements between each of the first filers. *See Pepsico,* 315 F.3d at 109-10 (rejecting hub and spoke conspiracy allegation for failing to prove connecting horizontal agreements amongst the spokes); *Actos*, 2015 U.S. Dist. LEXIS 127748, at *77 ("the plaintiff must demonstrate both that there was a horizontal agreement between the spoke defendants, and that each of those defendants was a 'knowing participant in that agreement and facilitated the scheme.'"). But there is neither direct nor circumstantial evidence of agreements between the first filers.

1. Even With A Full Discovery Record, There Is Not A Scintilla Of Evidence Of A Conspiracy

There is no direct evidence of conspiracy here, like "a recorded phone call in which two competitors agreed to fix prices at a certain level." *Mayor & Council of Baltimore v. Citigroup, Inc.*, 709 F.3d 129, 136 (2d Cir. 2011); *see also In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 324 n.23 (3d Cir. 2010) (Direct evidence consists of "evidence that is explicit and requires no inferences to establish the proposition or conclusion being asserted."). To the contrary, it is undisputed that the settlement agreements were separately and independently negotiated. DSUF ¶¶ 343-46. There is no record evidence that any generics discussed (let alone agreed to) the terms of their settlement agreement with anyone. DSUF ¶¶ 343-45. And Forest never shared information about ongoing settlement negotiations with any generic manufacturer. DSUF ¶ 346.

In the absence of direct evidence, DPPs must produce circumstantial evidence that "tends to exclude the possibility of independent action." *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 768 (1984). Because consciously parallel conduct is "as consistent with permissible competition as with illegal conspiracy [and] does not, standing alone, support an inference of conspiracy" (*Matshushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986)), DPPs must show the existence of "plus factors" that support an inference of an agreement. *See Mayor & Council of Baltimore v. Citigroup, Inc.*, 709 F.3d 129, 136 (2d Cir. 2013) (holding that plaintiffs must show that "interdependent conduct is accompanied by circumstantial evidence and plus factors" in order to prove a conspiracy exists). "These 'plus factors' may include: a common motive to conspire, evidence that shows that the parallel acts were against the individual economic self-interest of the alleged conspirator, and evidence of a high level of interfirm communications." *Id.* (quoting *Twombly v. Bell Atl. Corp.*, 425 F.3d 99, 114 (2d Cir.

2005), *rev'd on other grounds*, 550 U.S. 544 (2007)); *Actos*, 2015 U.S. Dist. LEXIS 127748, at *7 (same).

a. Settlement Agreements With Generic Entry Acceleration Clauses Were in Each First Filer's Self-Interest

Actions that are consistent with a firm's economic self-interest cannot, alone, support an inference of conspiracy. *See Mayor & Council of Baltimore v. Citigroup, Inc.*, 709 F.3d 129, 138 (2d Cir. 2013) (holding that an inference of conspiracy is improper where the actions of the alleged conspirators "made perfect business sense."); *Ross v. Am. Express Co.*, 35 F. Supp. 3d 407, 447 (S.D.N.Y. 2014) ("[N]o conspiracy should be inferred from ambiguous evidence or . . . mere parallelism when defendants' conduct can be explained by independent business reasons.") (quoting *In re Baby Food Antitrust Litig.*, 166 F.3d 112, 122 (3d Cir. 1999)) (second alteration in original), *aff'd* 630 Fed. Appx. 79 (2d Cir. 2015); *Cephalon*, 2014 U.S. Dist. LEXIS 84818, at *50-51 (acknowledging that agreements in contravention of each generic manufacturer's self-interest could suggest a conspiracy, but finding no conspiracy where the agreements with contingent entry clauses were in the generics' own self-interest).

Here, the first filers had independent reasons for agreeing to settle the Namenda patent litigation with Forest: the settlement agreements allowed them to end the patent litigation, thereby saving future litigation costs, coupled with an assurance they would remain a first entrant into the memantine market. *See Actos*, 2015 U.S. Dist. LEXIS 127748, at *79; *Cephalon*, 2014 U.S. Dist. LEXIS 84818, at *57-58; *see also* DSUF ¶¶ 337-40 (indicating the Generic Entry Acceleration Clauses permitted each first filer to enter the memantine market as early as any other generic manufacturer).

In *Actos*, Judge Abrams, faced with a nearly identical hub and spoke conspiracy allegation, rejected plaintiffs' claim, in part because the plaintiffs failed to allege that the

decisions to agree to the settlement agreements were against the generic manufacturers' self-interests. *See* 2015 U.S. Dist. LEXIS 127748, at *78-79 ("[T]here is no factual basis from which to infer that, on balance, the agreements were against the Defendants' self-interest."); *see also Nexium* 842 F.3d at 56 (same); *Cephalon*, 2014 U.S. Dist. LEXIS 84818, at *48, *59 (same).

Additionally, the Generic Entry Acceleration Clauses were valuable to each First Filing Generic Manufacturer because those clauses preserved their respective first filer rights under the Hatch-Waxman statutory scheme. *See Actos*, 2015 U.S. Dist. LEXIS 127748, at *15; DSUF ¶¶ 341-42. Defendant's expert economist, Dr. Lona Fowdur, analyzed DPPs' conspiracy allegations and opined that the claim was illogical as a matter of economics. Fowdur Rep. § VIII.C. Dr. Fowdur opined that it was in "the unilateral interest of each generic manufacturer to seek a settlement that preserves its first-filer rights to enter simultaneously with other first-filers, regardless of whether other first filers had similar clauses in their settlement agreements." *Id.* at ¶ 83. Dr. Fowdur's analysis stands unrebutted as none of DPPs' experts have even analyzed the issue. *See* DSUF ¶ 353. Because these clauses were in each first filer's self-interest, there is no basis, as an economic matter, to infer a conspiracy. *Id.*

The factual record supports this economic conclusion because it is undisputed that the Generic Entry Acceleration Clauses were demanded by each generic manufacturer in settlement negotiations with Forest. DSUF ¶ 352. Indeed, as several Forest executives testified, the first filers were not willing to settle without these provisions. Ryan (Sept. 7) Dep. 202:25-203:11 ("I don't think any of them would have settled without it."); Agovino Dep. 160:24-161:6 ("The generic companies wouldn't have settled without those provisions."). Because "there is no evidence that the bilateral settlements contravened the [first filer's] self-interest, and significant

evidence that the settlements were in line with their economic self-interests, . . . a fact-finder cannot draw an inference of conspiracy." *Actos,* 2015 U.S. Dist. LEXIS 84818, *58-59.

b. The Is No Evidence of Inter-firm Communications Among The Generic Manufacturers

As discussed, *supra*, despite obtaining discovery from nearly all of the first filers, there is no evidence that shows they spoke with one another regarding the settlement agreements, let alone reached agreements. *See supra* §§ III.A.1. As in *Actos*, there is no evidence that the generic manufacturers "communicated with each other in advance of entering the settlements, or that the agreements were negotiated together." *See* 2015 U.S. Dist. LEXIS 127748, at *79-80. The absence of any inter-firm communications between the generic manufactures suggesting an agreement is fatal to DPPs' argument that the generic manufactures agreed with one another to delay generic entry. *Id.*

c. There was No Common Motive to Conspire

Nor is any common motive to conspire present in this case. "[T]he absence of a rational motive to engage in the alleged conspiracy is 'highly relevant to whether a genuine issue for trial exists within the meaning of Rule 56(e);' if the defendants have 'no rational economic motive to conspire, and if their conduct is consistent with other, equally plausible explanations, the conduct does not give rise to an inference of conspiracy.'" *AD/SAT v. AP*, 181 F.3d 216, 233 (2d Cir. 1999) (quoting *Matsushita*, 475 U.S. at 596-97).

Here, rather than depending on the other first filers to join a supposed conspiracy, each generic manufacturer would have achieved a better outcome if the other first filers acted *contrary to* the interests of the alleged conspiracy by negotiating an earlier date and thereby triggering the Generic Entry Acceleration Clause. DSUF ¶¶ 354-55. Indeed, the *Cephalon* court recognized that Generic Entry Acceleration Clauses undermine a conspiracy theory because "[t]he Generic

[Manufacturers] had no reason to conspire amongst themselves when they could obtain the best deal by agreeing to [the brand's] term and hoping that the independent actions of other Generic [Manufacturer] would produce still a better deal." *Id.* at *62.

2. The Settlement Agreements Caused No Unreasonable Restraint of Trade

Even if DPPs could show an agreement among the first filing generic manufacturers, DPPs' conspiracy claims would fail for the additional reason that the settlement agreements had no anticompetitive effect. *See Pepsico*, 315 F.3d at 109 (requiring plaintiff show an agreement is an unreasonable restraint of trade under either a per se or rule of reason analysis); *Actos*, 2015 U.S. Dist. LEXIS, at *81 (only agreements that unreasonably restrain trade are outlawed by the Sherman Act.). As discussed, *supra*, the Namenda patent settlements had no anticompetitive effects because (1) the settlement agreements did not include an unlawful reverse payment and (2) the settlement did not cause any delay in generic entry. *See supra* §§ I, II. Summary judgment in favor of Forest on DPPs' conspiracy claims is therefore warranted.

IV. Forest is Entitled to Summary Judgment on DPPs' Hard Switch Claims Because DPPs Cannot Establish that Proposed Class Members Suffered Antitrust Injury as the Result of Forest's February 2014 Announcement

As outlined above, DPPs have the burden of establishing that they suffered "[an] injury of the type the antitrust laws were intended to prevent and that flows from that which makes the defendants' acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977); *see also Wellbutrin I*, 133 F. Supp. 3d at 762-63; *see also supra §* II.B. Where the claimed causal connection is ambiguous, there can be no antitrust injury. *See e.g.*, *Unitherm Food Sys. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1365 (Fed. Cir. 2004), *rev'd on other grounds* 546 U.S. 394 (2006) (rejecting antitrust liability where "[expert's] testimony gave no indication that he ever tried to differentiate harm attributable to [plaintiff]'s antitrust liability from harm

attributable to other [causes]"); *see also Ashley Creek Phosphate Co. v. Chevron USA*, 315 F.3d 1245, 1252 (10th Cir. 2003) (noting absence of a clear causal linkage foreclosed plaintiffs' antitrust injury). Courts in the Second Circuit have concluded that such ambiguity exists when, like here, plaintiffs cannot provide quantitative analyses that permit the court to infer the scale of damages, or where the cause of the alleged harm could be derived from "any number of legitimate business reasons." *U.S. Airways v. Sabre Holdings Corp.*, 105 F. Supp. 3d 265, 286-87 (S.D.N.Y. 2015) (finding antitrust injury to be absent when "price and product competition" were not "necessarily limited" by defendant's refusal to deal); *see also United States Football League v. Nat'l Football League*, 842 F.2d 1335, 1377-79 (2d Cir. 1988) (plaintiffs must demonstrate that defendants' unlawful acts, and not other factors, substantially contributed to their injuries); *Intimate Bookshop Inc. v. Barnes & Noble, Inc.*, No. 98-cv-5564, 2003 U.S. Dist. LEXIS 17231, at *25-26 (S.D.N.Y. Sept. 30, 2003) ("[Plaintiff]'s unsupported assumption of causation and supposition that all of its losses were caused by defendants' allegedly unlawful conduct, and failure to account for defendants' lawful conduct and intervening market factors are fatal to its claim"); *Drug Mart Pharm. Corp. v. Am. Home Prod. Corp.*, No. 93-cv-5148, 2012 U.S. Dist. LEXIS 115882, at * 44-48 (E.D.N.Y. Aug. 16, 2012) ("where the evidence of lost sales is as *de minimis* as it is here [under 3%], it cannot support a finding of a causal connection between lost sales and the alleged [anticompetitive conduct].").

A. The Court Provided DPPs with a Framework for Proving Antitrust Injury

The Court has already set out the evidentiary hurdles that DPPs need to clear in order to satisfy their burden on antitrust injury. *See Namenda I*, at *38-39. Specifically, the Court explained that DPPs would need to prove that (1) "patients switched to Namenda XR because of the announced withdrawal of Namenda IR"; (2) DPPs "were forced to pay for certain patients'

memantine treatment at brand-name prices because the patients switched to Namenda XR prior to the entry of the injunction"; and (3) DPPs paid for these patients' use of "Namenda XR after generic entry" because this subset of patients never switched back to generic Namenda IR. *Id.* The Court's framework highlights the importance of the timing of any such switching, and, more importantly, the reason why those patients switched, in determining whether there was in fact antitrust injury, given that the "hard switch" consisted solely of the announcement of the ultimately thwarted withdrawal, and the "injunction blunted much of the success of Forest's 'hard switch.'" *Id.* at *30. Additionally, the Court reiterated in its May 23, 2017 collateral estoppel decision that the question of antitrust injury remained an open one, and that DPPs still needed to "prove that the defendants' illegal conduct resulted in antitrust injury to the plaintiff." *Namenda II*, at *51-52. Because DPPs' experts expressly disavow any assessment of patient switching to or from Namenda XR, and thus have no way of attributing alleged overcharges to switching caused exclusively by Forest's announcement, DPPs fall short of the antitrust injury requirement as a matter of law.

B. DPPs' Experts Ignored the Court's Guidance and Failed to Assess Which Patients, if Any, Switched as a Result of the February 2014 Announcement

Despite the Court's express guidance on what would be necessary to prove antitrust injury, DPPs' causation and damages expert, Dr. Lamb, concedes that his proposed damages model does not account for whether individuals switched to Namenda XR only as the result of the announcement. Lamb (Oct. 6) Dep. 56:7-21 (conceding his damages will likely include XR sales that were not tainted by any anticompetitive conduct); *id.* 48:8-49:3 (conceding his methodology is unable to exclude first-time memantine patients over time, which means his damages include all XR volume after generic entry in July 2015, without regard to when patients first began taking XR); *see also* Memo. in Supp. of Mot. to Exclude Certain Ops. And Proposed

Testimony of Dr. Russell Lamb ("Lamb Daubert") at 9-10. Not only did Dr. Lamb make no attempt to comply with the Court's antirust-injury framework, he criticized Forest's experts for doing so. *See* Amended Expert Reply Report, Dr. Russell Lamb ("Lamb Rep. II") ¶¶ 60-61; *see also id.* ¶¶ 29, 79. Dr. Lamb is wrong to disregard the Court's antitrust-injury framework. When a court expressly articulates the law as it applies to the facts of the case, as it did here for antitrust injury, that is the applicable "law of the case," and the "decision should continue to govern the same issues in subsequent stages in the same case." *Legal Aid Soc'y v. City of New York*, 114 F. Supp. 2d 204, 224 (S.D.N.Y. 2000) (citing *Arizona v. California*, 460 U.S. 605, 618-19 (1983)).

Instead, Dr. Lamb chose to take a shortcut with respect to antitrust injury: He assumed, despite considerable evidence suggesting otherwise, that ***any and all*** Namenda XR adoption in the real world that exceeded the estimated adoption rates in Forest's projections (from before its decision to remove Namenda IR) ***are entirely attributable to the February 2014 announcement***. Lamb Rep. I. ¶¶ 146, 150-57; Lamb (Oct. 6) Dep. 46:13-24 ("Q: . . . [Y]our model assumes that all actual Namenda XR days of therapy above your but-for estimate consists of the anticompetitive hard switches at issue in this case? A: I think that's a fair way of characterizing it, sir."); *id.* 45:23-46:12; 64:19-65:9; 66:4-20; Lamb Daubert at 2. But the Court was correct to note that the relevant question in assessing whether DPPs suffered antitrust injury here is not simply whether a patient switched from Namenda IR to Namenda XR, as Dr. Lamb contends, but rather ***the reason why that patient switched***. DPPs' expert economist, Dr. Ernst Berndt, made the same mistake, conceding that he did no econometric analysis (e.g., regression analysis controlling for other factors) of whether increased Namenda XR adoption was the result of anything other than the February 2014 announcement. Berndt Dep. 183:9-15 ("Q. Dr. Berndt,

nowhere in your two reports do you do any sort of econometric assessment or analysis to evaluate what caused the increased conversion from Namenda IR to Namenda XR in the first quarter of 2014; am I right? A. That's correct."); 185:22-187:7 ("Q. And it's fair to say you haven't done any sort of regression or econometric model to look at other potential market events to deduce whether or not it was only favorable placement on Optum's formulary and the announcement of the planned withdrawal that caused increased conversion in early 2014; is that fair? . . . A. I have not undertaken any econometric analysis."). Without confirming that the February 2014 Namenda IR discontinuation announcement actually coerced specific patients or prescribing physicians to switch to Namenda XR, DPPs cannot establish that their alleged injury was the proximate cause of Forest's allegedly anticompetitive conduct, *Gatt Communs. Inc. v. PMC Assocs., LLC*, 711 F.3d 68, 76-77 (2d Cir. 2013), and cannot separate any purported damages arising from the February 2014 announcement from otherwise lawful conduct. *See U.S. Airways*, 105 F. Supp. 3d at 286-87; *United States Football League*, 842 F.2d at 1377-79; *Intimate Bookshop*, 2003 WL 22251312, at *25-26; *see also MCI Communications Corp. v. American Tel. & Tel. Co.*, 708 F.2d 1081, 1162 (7th Cir. 1982) ("When a plaintiff improperly attributes all losses to a defendant's illegal acts, despite the presence of significant other factors, the evidence does not permit a jury to make a reasonable and principled estimate of the amount of damage."); *Coleman Motor Co. v. Chrysler Corp.*, 525 F.2d 1338, 1353 (3d Cir. 1975) ("we cannot permit a jury to speculate concerning the amount of losses resulting from unlawful, as opposed to lawful, competition."); *cf.* Berndt Dep. 134:1-5, 185:22-187:7 (conceding he did no assessment of formulary placement, pricing, or marketing as other possible reasons for Namenda XR adoption).

C. DPPs' Experts Also Failed to Do Any Analysis of Whether Patients Who Allegedly Switched as the Result of the February 2014 Announcement Actually Stayed on Namenda XR

Further, DPPs' experts ignore other important events that took place after the February 2014 announcement that indisputably affected Namenda XR adoption—such as the announcement in June 2014 that the discontinuation had been delayed, the NYAG Action injunction, and the announcements of continued availability mandated by the injunction—and fail to analyze whether those events led to patients switching back or "reverse commuting" to Namenda IR prior to generic entry in July 2015. Lamb (Oct. 6) Dep. 188:18-189:16 (conceding that his model cannot discern reverse commuting due to Namenda XR supply issues). Again, this failure is critical because if individuals switched to Namenda XR as the result of the February 2014 announcement (which DPPs cannot prove) but switched back to Namenda IR prior to generic entry in July 2015, those patients would not have caused DPPs to purchase additional Namenda XR post-July 2015 (and there would be no antitrust injury). *Namenda I*, at *38-39; *see also* Lamb Daubert 9-10.

DPPs' experts do no quantitative analysis to assess or rule out the effect of these post-announcement events. Lamb (Oct. 6) Dep. 97:6-100:14 (noting that Dr. Lamb "didn't see other causes" for the structural break in February outside of those he believed to be encompassed by his view of the "hard switch strategy"); Lamb (Nov. 10) Dep. 127:7-21 (noting that the three bases for Dr. Lamb's opinion on post-injunction switching are "sales of Namenda XR before the injunction[,]" "Forest's own forecasts of Namenda XR penetration[,]" and "the documentary record of communications from Forest referencing the appeal."); Berndt Dep. 201:22-202:2 ("Q. . . . Am I right you've done no quantitative assessment of the effect of the post-injunction real-world conversion rates in this case; is that right? A. That is correct."); *see also* Lamb Daubert 2,

17. For example, in June 2014, due to a shortage in Namenda XR, Forest announced that it would postpone its planned withdrawal of Namenda IR. DSUF ¶¶ 410-12. Dr. Lamb concedes that his analysis would not account for individuals that switched back to Namenda IR during the Namenda XR shortage in the summer of 2014. Lamb (Oct. 6) Dep. 188:18-189:16. The undisputed evidence confirms that a significant number of patients indeed switched back to Namenda IR during that time. DSUF ¶ 412. Later that year, after the NYAG launched its investigation into Forest's planned withdrawal, Forest entered into a standstill agreement, where it promised not to remove Namenda IR from the market pending the conclusion of the NYAG Action. DSUF ¶¶ 413-15. Dr. Lamb did no analysis of the effect of the standstill agreement on Namenda XR adoption. Lamb (Nov. 10) Dep. 107:1-108:14 (noting Dr. Lamb only ran his structural break for February 2014)); *see also* Lamb Daubert at 5..

Most importantly, Judge Sweet issued an injunction preventing Forest from withdrawing Namenda IR, which the Court has acknowledged, as DPPs should have, "blunted much of the success of Forest's 'hard switch.'" *Namenda I*, at *50. The NYAG confirmed that the injunction "was effective in protecting competition in the relevant market." DSUF ¶¶ 491-95. Yet Dr. Lamb assumes the injunction had *no effect* in undoing any anticompetitive effects of the February 2014 announcement. *See* Lamb Rep. I ¶¶ 106-18; Lamb Rep. II ¶¶ 69-75. Indeed, DPPs' experts did no analysis whatsoever to confirm whether any patients that may have switched to Namenda XR due to the announcement switched back to Namenda IR after the injunction, and thus whether wholesaler purchases after July 2015 would have been affected at all by any such patients. DSUF ¶¶ 464-473; Berndt Dep. 201:22-202:2.

Nor does Dr. Lamb quantify or assess the offsetting effects of Forest's January 2015 "continued availability" announcements had on Namenda XR adoption, instead arguing that they

were actually harmful, without doing any quantitative work to confirm his assertion. Lamb (Nov. 10) Dep. 115:20-117:23. Under the terms of the injunction, Forest was required to "inform healthcare providers, pharmacists, patients, caregivers, and health plans of this injunction (and provide a copy of the injunction or other means to easily view the injunction) and the continued availability of Namenda IR in the same or substantially similar manner in which they informed them of Forest's plan to discontinue Namenda IR in February 2014." DSUF ¶¶ 484-486; *see also Namenda II*, at *4, 25 (recognizing that injunction required "Forest to affirmatively undo the effects of its announcement of the withdrawal"). Forest fully complied. DSUF ¶ 485. Specifically, during the period between December 2014 and June 2015, Forest undertook steps designed to undo any purported effects of the February 2014 announcement, including posting the injunction to the Namenda website and sending over 900,000 emails to doctors and caregivers. DSUF ¶¶ 400, 485; Snyder Decl. ¶¶ 4-5. Yet Dr. Lamb's methodology assumes that these continued-availability announcements, which were designed to mirror the February 2014 announcement efforts, had no effect on doctors and patients. Lamb (Nov. 10) Dep. 115:20-117:23 (claiming without support that Forest's communications were designed to "to raise the specter" of uncertainty in "this marketplace"). Similarly, Dr. Berndt made no effort to quantify the effect of these announcements on patients switching back to Namenda IR prior to generic entry. Berndt Dep. 68:22-69:6.

Lastly, DPPs cannot identify which individuals, if any, that allegedly switched to Namenda XR as the result of the February 2014 announcement actually stayed on Namenda XR beyond the July 2015 generic entry date to create the "overcharge" purchases DPPs allege. DSUF ¶¶ 474-83. Indeed, Dr. Berndt, whose opinion in the NYAG was focused on the likelihood of "reverse commuting" if Forest actually removed Namenda IR from the market, concedes that

he did no analysis of whether individuals switched to generic Namenda IR in the real world where Forest was prevented from executing the hard switch. Berndt Dep. 202:23-203:10 ("Q. And in this case, in your two reports, you don't analyze or offer any opinions as to whether there actually was reverse commuting, as you described it, in the real world after July [2015]; correct? . . . A. I don't analyze that, no. Q. And you don't do any quantitative analysis of whether patients actually switched from Namenda XR to generic Namenda IR in the real world after July 11, 2015, when generics entered; is that fair? . . . A. That is correct."). Yet, paradoxically, he acknowledges that the reality that managed care likely is seeking to force Namenda XR patients back to the generic Namenda IR product through various drug utilization tools, such as favorable formulary placement, step edits, and prior authorizations. Berndt Dep. 204:11-17 ("Q. You would expect that insurance companies, PBMs, managed care generally, are looking to move patients from Namenda XR to the less-expensive generic Namenda IR, using some of the various utilization tools that we've talked about; right? . . . A. Yes.").

As DPPs have ignored entirely the Court's framework for proving antitrust injury from the hard switch, the Court should grant summary judgment for Forest on those claims.

CONCLUSION

For the foregoing reasons, the Court should grant Forest's Motion for Summary Judgment.

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Respectfully submitted,

Martin M. Toto
Heather K. McDevitt
Ryan P. Johnson
Kristen O'Shaughnessy
WHITE & CASE LLP

1221 Avenue of the Americas
New York, New York 10020
Telephone: (212) 819-8200

J. Mark Gidley
Peter J. Carney
WHITE & CASE LLP
701 Thirteenth Street, NW
Washington, DC 20005
Telephone: (202) 626-3600

Kevin C. Adam
WHITE & CASE LLP
75 State St.
Boston, MA 02109
Telephone: (617) 979-9321

Counsel for Defendants Actavis plc, Forest Laboratories, LLC, Forest Laboratories, Inc., and Forest Laboratories Holdings Ltd.